

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

Membership of the Working Party for producing the Guidance Notes for dental practitioners on the safe use of x-ray equipment

BRITISH DENTAL ASSOCIATION (BDA)

Dr J Mooney, GDP, Bury

BRITISH SOCIETY OF DENTAL AND MAXILLOFACIAL RADIOLOGY (BSDMFR)

ROYAL COLLEGE OF RADIOLOGISTS (RCR)

Mr P N Hirschmann, Leeds Dental Institute

FACULTY OF GENERAL DENTAL PRACTITIONERS (UK) OF THE ROYAL COLLEGE OF
SURGEONS OF ENGLAND (FGDP-RCS)

Mr M Williams, GDP, Langar

HEALTH AND SAFETY EXECUTIVE (HSE)

Dr J R Gill, Technology Division, Bootle

INSTITUTE OF PHYSICS AND ENGINEERING IN MEDICINE (IPEM)

Mrs A Walker, North Western Medical Physics, Christie Hospital, Manchester

NATIONAL RADIOLOGICAL PROTECTION BOARD (NRPB)

Mr A P Hudson, Leeds (Editor)

Mr I D Napier, Leeds

Observer

DEPARTMENT OF HEALTH (DH)

Mr I Cooper, Senior Dental Officer

© National Radiological Protection Board – 2001.

[The copyright is held by NRPB on behalf of the organisations represented on the Working Party].

'NRPB' is a registered trade mark of the National Radiological Protection Board.

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

British Dental Association

British Society of Dental and Maxillofacial Radiology

Royal College of Radiologists

Faculty of General Dental Practitioners (UK) of the Royal College of Surgeons of England

Health and Safety Executive

Institute of Physics and Engineering in Medicine

National Radiological Protection Board

Foreword

The safe and effective use of x-ray equipment is important to the protection of the patient, other members of the public and all members of the dental team. The risks associated with the necessary exposure to ionising radiation may be substantial, and must be minimised through meticulous adherence to good practice as set out in the following guidelines.

These well-written, unambiguous guidelines are comprehensive yet conveniently presented. Building on considerations of administrative infrastructure and practical and procedural aspects of dental radiology, the guidelines helpfully deal with key issues pertaining to equipment, quality assurance, notification, risk management, training, protection files, testing and essential legal requirements – matters all fundamental to good working practice.

The authors of the guidelines and the organisations they represent are to be congratulated on the thoroughness and outcome of the considerable body of work, which has led to this publication. In commending the guidelines to all general dental practitioners, I would wish to emphasise, as highlighted in the guidelines, that all radiographic examinations should have a net benefit for the patient with the exposure to ionising radiation being optimised for the intended purpose. I must also stress that all members of the dental team engaged in any aspect of radiography must be appropriately and adequately trained and have up-to-date knowledge and relevant skills.

Radiographic examinations offer incalculable benefits to patients and as such properly form an integral element of everyday clinical practice. Each and every use of ionising radiation must, however, be safe and effective. Application of the following guidance will greatly assist in the realisation of this goal.

NAIRN H F WILSON

President

The General Dental Council

June 2001

Preface

Dental radiographic examinations represent one of the most frequently undertaken radiological investigations in the UK. A survey for the period 1997/98⁽¹⁾ estimated that dentists were taking 19 million intra-oral radiographs each year and more than 2.9 million panoramic radiographs. The effective dose delivered to the patient per radiograph is very small but the collective dose is significant because of the large number of radiographs that are taken.

New general recommendations from the International Commission on Radiological Protection were issued in 1991⁽²⁾. As a result, revised Euratom Directives were published and addressed the protection of workers and the general public (in 1996)⁽³⁾, and patient protection (in 1997)⁽⁴⁾. These Directives had to be implemented by member states of the EU by 13 May 2000, and this has resulted in the UK in the creation of two new sets of regulations:

- (a) the Ionising Radiations Regulations 1999 (IRR99)⁽⁵⁾ which relate principally to the protection of workers and the public, but also address the equipment aspects of patient protection;
- (b) the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R2000)⁽⁶⁾ which relate to patient protection.

These 'Guidance Notes for Dental Practitioners' have been drafted by a small Working Party representing the organisations listed below and the content should be regarded as representative of good working practice:

British Dental Association
British Society of Dental and Maxillofacial Radiology
Royal College of Radiologists
Faculty of General Dental Practitioners (UK) of the Royal College of Surgeons of England
Health and Safety Executive
Institute of Physics and Engineering in Medicine
National Radiological Protection Board

The Working Party wishes to thank the Standing Dental Advisory Committee of the Department of Health for its support of the technical content of the Guidance Notes, and to gratefully acknowledge the Department of Health's decision to fund both the publishing and distribution of the final document.

The aim is to provide dental practitioners with a convenient publication upon which to evaluate and base their compliance with those parts of the new regulations that apply to the use of x-rays in a dental practice. The drafting was undertaken under an informal agreement between the British Dental Association (BDA), the Institute of Physics and Engineering in Medicine (IPEM) and the National Radiological Protection Board (NRPB). IPEM has revised the more general Guidance Notes that relate to both medical and dental uses of ionising radiation⁽⁷⁾ and which apply principally to the hospital environment.

Contents

Foreword	ii
Preface	iii
Chapter 1 Introduction	1
<i>Application</i>	1
<i>Legislation</i>	1
<i>Radiation risks</i>	2
<i>Structure and purpose of this document</i>	3
<i>Legal compliance</i>	3
<i>Clinical governance</i>	4
Chapter 2 Administrative infrastructure for dental radiology outside of the hospital sector	5
<i>Legal responsibility and staff appointments</i>	5
Introduction	5
<i>Legal Person</i>	5
Radiation Protection Supervisor	5
<i>Referrer</i>	5
Practitioner (<i>IRMER practitioner</i>)	6
Operator	6
<i>External appointments</i>	7
Radiation Protection Adviser	7
Medical Physics Expert	8
<i>Notification of specified work</i>	8
<i>Research</i>	8
<i>Risk assessment for ionising radiation</i>	9
<i>Dose limitation for workers and the public (excluding patients)</i>	10
<i>Training</i>	11
<i>Radiation Protection File (Local Rules and Legal Person's Procedures)</i>	11
<i>Duties of employees</i>	12
<i>Administrative and procedural aspects of patient protection</i>	12
Referral	12
Justification	13
Medico-legal and other third-party exposures	13
Female patients of child-bearing age	14
Optimisation	15
'Excessive' exposure of patients	16
<i>Quality assurance</i>	17

Chapter 3	Practical and procedural aspects of dental radiology	18
	<i>Introduction</i>	18
	<i>Controlled area</i>	18
	<i>Classification of staff and personal dosimetry</i>	19
	<i>Location and installation</i>	19
	<i>Room warning signs and signals</i>	21
	<i>Maintenance and testing</i>	21
	<i>General procedures</i>	22
	<i>Detectors, processing and viewing</i>	24
	Film	24
	Digital detectors	24
	<i>Procedures specific to intra-oral radiography</i>	25
	<i>Procedures specific to panoramic radiography</i>	25
	<i>Procedures specific to cephalometry</i>	26
	<i>Protective clothing</i>	26
Chapter 4	Equipment aspects for dental radiology	27
	<i>Introduction</i>	27
	<i>General</i>	27
	<i>X-ray source assembly</i>	27
	<i>Beam filtration</i>	27
	<i>X-ray tube operating parameters</i>	28
	<i>Beam size, beam alignment, film holders and distance control</i>	29
	Intra-oral radiography	29
	Panoramic radiography	29
	Cephalometry	30
	<i>Warning signals</i>	30
	<i>Exposure control</i>	30
Chapter 5	Quality assurance in dental radiography	32
	<i>Introduction</i>	32
	<i>QA programme</i>	32
	<i>QA procedures for image quality</i>	33
	Image quality	33
	Unacceptable radiographs	34
	<i>QA procedures for patient dose and x-ray equipment</i>	34
	<i>QA procedures for the darkroom, desktop processing units, films and processing</i>	35
	Darkroom and desk top processing units	35
	Films and processing	35
	<i>QA of working procedures</i>	36
	Radiation Protection File (Local Rules and <i>Legal Person's</i> Procedures)	36
	Operational procedures	36
	Procedures log	36

QA procedures for training	37
QA audits	37
Appendix 1 Particulars to be provided in a notification of specified work under Regulation 6(2) of IRR99	38
Appendix 2 Matters relevant to a risk assessment in pursuance of Regulation 7(1) of IRR99	39
Appendix 3 Adequate training requirements under IR(ME)R2000	41
<i>Adequate training</i>	41
<i>Continuing education and training</i>	42
Appendix 4 Essential content of radiation protection file	44
<i>Content deriving from IRR99</i>	44
Local Rules	44
Working instructions	45
Contingency arrangements	45
Dose investigation level	46
<i>Content deriving from IR(ME)R2000</i>	46
<i>Legal Person's procedures</i>	46
Patient identification	47
Staff appointments	47
Accidental or unintended dose	47
Appendix 5 Guidance on the testing of dental x-ray equipment	48
<i>'Critical examination'</i>	48
<i>'Acceptance test'</i>	49
<i>'Routine test'</i>	49
<i>Results of tests</i>	50
Appendix 6 Essential legal requirements	51
<i>Essential legal requirements arising out of IRR99</i>	51
<i>Essential legal requirements arising out of IR(ME)R2000</i>	52
Appendix 7 Useful addresses and list of abbreviations employed in these Guidance Notes	53
<i>Useful addresses – organisations</i>	53
<i>Useful addresses – professional bodies</i>	55
<i>Abbreviations used in this document</i>	56
References	57

1 Introduction

Application

- 1.1** These Guidance Notes (GNs) apply to the use of equipment specifically designed for radiography of the teeth or jaws including radiography using an intra-oral image receptor (or, with the same equipment, an extra-oral receptor), panoramic radiography with an extra-oral x-ray tube and cephalometric radiography. While primarily concerned with the use of x-ray equipment for the examination of patients, the guidance is also relevant to its operation during testing, measurement of the radiation produced, staff training, research into examination techniques, the examination of volunteers in approved research projects and other uses at the place where the equipment is normally used.
- 1.2** The GNs have been written to relate specifically to the use of dental x-rays outside the hospital sector. The area of use does not materially affect the technical aspects of radiation protection; consequently, the technical content of Chapters 3 and 4 is universal to the use of x-rays in all areas of dentistry. However, practitioners working outside the hospital sector do not, for example, have immediate access to specialist medical physics backup nor the support of a hospital administrative structure. Consequently, the content of Chapter 2 and, to a lesser extent, Chapter 5 reflects an administrative infrastructure that is very different to that found in a hospital. Additionally, the content of the majority of the appendices is designed to assist the 'stand alone' practitioner who does not have day-to-day, on-site access to specialist technical advice. Staff working in community health trusts might find themselves working within an administrative structure that is most closely related to the content of these GNs.

Legislation

- 1.3** All dental practices have to arrange their work to comply with health and safety legislation, such as the general duties of the Health and Safety at Work etc Act 1974⁽⁸⁾, the Management of Health and Safety at Work Regulations 1999 (MHSWR99)⁽⁹⁾ and the Provision and Use of Work Equipment Regulations (1998)⁽¹⁰⁾. This is not the concern of these GNs, although some passing references are made to the more general legislation where this is considered to assist the principal aim of achieving compliance with the two sets of radiation protection legislation that follow.
- 1.4** The Ionising Radiations Regulations 1999 (IRR99)⁽⁵⁾ relate principally to the protection of workers and the public, but also address the equipment aspects of patient protection. HSE has published an accompanying Approved Code of Practice (ACoP) and associated Guidance⁽¹¹⁾.

- 1.5** The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R2000)⁽⁶⁾ relate to patient protection. Supporting guidance and notes on good practice are available on the Department of Health's web-site.

Radiation risks

- 1.6** An evaluation of the risks associated with a range of diagnostic radiological procedures, including dentistry, may be found in a report of an advisory group on ionising radiation, entitled 'Guidelines on Patient Dose to Promote the Optimisation of Protection for Diagnostic Medical Exposures'⁽¹²⁾.

- 1.7** Many individual diagnostic procedures deliver only a relatively small radiation dose, and this is especially true in dentistry. However, the above named Guidelines state:

'Diagnostic investigations utilising ionising radiations offer potential benefits to the health care of patients and are an accepted part of medical practice. However, it is recognised that exposure to such radiations is associated with an increased risk in the long term of malignant disease in those persons irradiated; there is also a putative but low risk of serious hereditary disease in their descendants. Furthermore, it is assumed that the probability of occurrence of these adverse effects is directly proportional to the level of exposure, without any dose threshold. On this basis, it is necessary to consider the potential harm, albeit relatively small, arising from even the lowest levels of absorbed radiation dose and to avoid those exposures which have no merit.'

- 1.8** The first stage in eliminating unnecessary exposure is to ensure that any radiographic examination that is undertaken has a net benefit for the patient and will normally provide new information to aid the patient's management or prognosis (ie that it is 'Justified', as developed in paragraphs 2.32 to 2.35).

- 1.9** A number of publications⁽¹³⁾⁽¹⁴⁾ have drawn attention to the poor quality of many dental radiographs, to the point where a significant proportion may be of no practical clinical value. It is particularly important in dental radiation protection to 'avoid those exposures which have no merit'. This amounts to achieving a marked improvement in radiographic techniques to the point where, ideally, all radiographs are of adequate diagnostic quality.

- 1.10** Having attempted to eliminate these 'exposures which have no merit' it is necessary to reduce routine patient doses to as low as reasonably practicable consistent with the intended purpose (known as 'Optimisation'). A practical aid to achieving this is the concept of the 'Diagnostic Reference Level', which can be found in paragraphs 2.47 to 2.49 of these GNs.

Structure and purpose of this document

- 1.11** This document consists of five chapters, supported by seven technical appendices that provide more detailed guidance on specific topics of particular importance in terms of meeting legal requirements. The purpose is to provide the dental practitioner with comprehensive guidance to enable dental radiology to be undertaken in accordance with:
- (a) the requirements of IRR99;
 - (b) the requirements of IR(ME)R2000;
 - (c) established principles of good practice.
- 1.12** A prime objective of this document is to provide an operational structure within which dental practitioners can work to eliminate ‘exposures which have no merit’ and to ‘optimise’ all justified exposures. To this end the Working Party places great emphasis on the value of Quality Assurance (QA), as detailed in Chapter 5.

Legal compliance

- 1.13** For the convenience of the reader, the **Essential Legal Requirements** have been summarised in Appendix 6, together with a simple indexing system to locate the primary source(s) of information relating to these requirements.
- 1.14** Within the text of this document, the following hierarchy of requirements and recommendations has been followed:
- (a) where legal requirements are obvious, they are directly linked to the relevant regulation;
 - (b) where the direct link to a specific regulation is omitted, the word ‘must’ is used to denote a legal requirement;
 - (c) the word ‘should’ relates to requirements that can be linked, directly or indirectly, to the ACoP or to the formal guidance that supports either IRR99 or IR(ME)R2000, and in a few cases to a direct requirement from a British Standard;
 - (d) phrases like ‘recommended’, ‘advised’ and ‘would be expected’ are used where the suggested action has no specific legal backing, but represents the Working Party’s interpretation of what is necessary to achieve good practice.
- 1.15** The ACoP gives practical advice on how to comply with the law. A *Legal Person* (see paragraph 2.2) following this advice will be doing enough to comply with the law in respect of those specific matters on which the ACoP gives advice. A *Legal Person* may use alternative methods to those set out in the ACoP in order to comply with the law. However, the ACoP has a special legal status. If a *Legal Person* is prosecuted for breach of the law, and it is proved that the relevant provisions of the ACoP have not been followed, then the *Legal Person* would need to demonstrate that compliance with the law had been

achieved in some other way. Failure to demonstrate this would mean that a court would find the *Legal Person* to be at fault.

- 1.16** It is not compulsory to follow guidance that supports regulations or an ACoP and the *Legal Person* is free to take other action. However, a *Legal Person* who does follow such guidance will normally be regarded as doing enough to comply with the law. Inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

Clinical governance

- 1.17** Practitioners should regard observance of the recommendations and standards laid out in these GNs as part of the implementation of clinical governance in their practices. The GNs may also be used as an appropriate standard against which the quality of activities can be measured during a peer review or a clinical audit.

2 Administrative infrastructure for dental radiology outside the hospital sector

Legal responsibility and staff appointments

2.1 Introduction

This section describes the responsibilities and staff appointments required under IRR99 and IR(ME)R2000. In many dental practices the responsibilities and appointments could fall on one and the same person.

2.2 Legal Person

Responsibilities under the IRR99 relate to an 'employer' and a 'radiation employer', whilst IR(ME)R2000 uses only 'employer' but with a definition based on the concept of responsibility rather than employment law. What matters is that there is a clearly defined person or body corporate that takes **legal responsibility** for implementing both sets of regulations. Consequently it is recommended that the Local Rules (see paragraphs 2.24 and 2.27 and Appendix 4) specify the person or body corporate with that legal responsibility in respect of every dental x-ray set and every item of auxiliary equipment that is associated with radiation safety. In these GNs that person or body corporate is referred to as the *Legal Person*.

2.3 Radiation Protection Supervisor

Where a controlled area is designated (see paragraphs 3.2 to 3.5), the *Legal Person* must appoint one or more Radiation Protection Supervisors (RPSs) whose function is to help in ensuring compliance with IRR99 and in particular to supervise the arrangements set out in the Local Rules. Similar appointments are recommended even in situations where no controlled area is designated.

Appointed RPSs must have received appropriate training (see paragraph 2.20) and should be closely involved with the radiography. An appropriate appointee is likely to be a dental practitioner or another Professional Complementary to Dentistry (PCD), such as a dental nurse. Whoever is appointed as an RPS should have the authority to adequately implement their responsibilities.

2.4 Referrer

In IR(ME)R2000, a *referrer* means a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the *Legal Person's* procedures to refer individuals for medical exposure to an *IRMER practitioner* (see paragraph 2.5).

In the dental surgery the *referrer* will normally be a dental practitioner who wishes to

refer patients to an *IRMER practitioner* for a radiographic examination. As at January 2001, it is not permissible for a PCD to act as a *referrer*. See paragraphs 2.29 and 2.31 for guidance on referrals.

2.5 Practitioner (IRMER practitioner)

In IR(ME)R2000, a 'practitioner' means a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the *Legal Person's* procedures to take responsibility for an individual medical exposure. The primary function of the practitioner is to undertake the justification of individual exposures (see paragraphs 2.32 to 2.34). All practitioners must be adequately trained to undertake this function (see Appendix 3 for details). To distinguish the practitioner as defined in IR(ME)R2000 from other staff groups also known as practitioners, the term *IRMER practitioner* will be used throughout these GNs.

2.6 Operator

In IR(ME)R2000 an operator is any person who is entitled, in accordance with the *Legal Person's* procedures, to carry out all or part of the practical aspects associated with a radiographic examination. Practical aspects include:

- (a) patient identification;
- (b) positioning the film, the patient and the x-ray tube head;
- (c) setting the exposure parameters;
- (d) pressing the exposure button to initiate the exposure;
- (e) processing films;
- (f) clinical evaluation of radiographs;
- (g) exposing test objects as part of the QA programme.

In fact, any single exposure could involve a number of different *operators* performing the various functions. Because of this range of functions carried out by *operators*, it is essential that the functions and responsibilities of individual *operators* are clearly defined by the *Legal Person*.

In dental practice it will be common for the *referrer* and *IRMER practitioner* to be the same person, who may also act as an *operator*. However, many dental nurses or other PCDs will also perform some of the functions of an *operator*. All *operators* must be adequately trained to undertake these functions (see Appendix 3 for details).

Non-clinical staff (eg practice managers and receptionists) should not normally be asked to undertake the majority of *operator's* duties. Some of the more straightforward *operator's* duties may be undertaken by non-clinical staff, but these staff must have been appropriately trained for all of the tasks that they perform and their training must be recorded.

External appointments

2.7 Radiation Protection Adviser

- (a) From time to time every *Legal Person* will need advice on compliance with IRR99, particularly those matters listed in paragraph (b) below. Such advice must be obtained by consulting a suitable Radiation Protection Adviser (RPA) (see paragraph (c) below) who must be appointed in writing and whose written appointment must include the scope of advice that is required. The *Legal Person* may appoint the RPA on a temporary basis for the purpose of obtaining the specific advice that is currently required. However, most dental practices would find it advantageous to appoint an RPA on an ongoing basis. This would ensure that advice is always available and that continuity of advice is assured. The person or organisation that provides routine radiation surveys of the dental equipment would normally be expected to be able to act as RPA, provided the criteria set out in paragraph (c) below are met.

The *Legal Person* is recommended to obtain key RPA advice in written format since this provides firm evidence that consultation has taken place.

- (b) The scope of advice that the *Legal Person* will require from the RPA, to meet statutory obligations, will include items that are mandatory by virtue of Schedule 5 of IRR99 (asterisked below) and items that derive from the ACoP:
- implementation of the requirements for designated areas*;
 - prior examination of plans for the installation and acceptance into service of new or modified dental x-ray equipment, with particular respect to any engineering controls, design features, safety features and warning devices provided to restrict exposure to ionising radiation*;
 - advice on the suitability, use and checking of any instrument provided to monitor levels of ionising radiation* (it is recognised that such instruments are currently of little practical value for staff in a dental practice);
 - the periodic examination and testing of engineering controls, design features, safety features and warning devices*;
 - the regular checking of systems of work provided to restrict exposure*;
 - the risk assessment;
 - the drawing up of contingency plans. (see Appendix 4, paragraphs A4.8 to A4.11);
 - the training of staff;
 - the assessment and recording of radiation doses received by staff, where this is applicable (see paragraphs 3.7 and 3.8);
 - the conduct of any investigations, required by the regulations (eg following an incident or accident situation);
 - the QA programme.

- (c) The RPA consulted must be able to demonstrate compliance with the HSE's current criteria of competence for RPAs⁽¹⁵⁾. The *Legal Person* must ensure that any RPA consulted is suitable in terms of possessing specific knowledge and adequate experience of radiation protection in dentistry.

2.8 Medical Physics Expert

A Medical Physics Expert (MPE) is defined in IR(ME)R2000 as 'a person who holds a science degree or its equivalent and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation'. The MPE would be expected to give advice on such matters as the measurement and optimisation of patient dose. A properly certificated and suitable RPA (see paragraph 2.7(c)) would be expected to be able either to act as the MPE or to suggest an appropriate person.

Notification of specified work

- 2.9** The *Legal Person* is required by regulation 6(2) of IRR99 to provide HSE with the particulars specified in Schedule 2 of the regulations (see Appendix 1 to these GNs). However, if a practice has already notified HSE under IRR85, there is no need to duplicate that notification under IRR99.

- 2.10** Changes that materially alter the particulars notified to HSE must be re-notified. Examples are a change in ownership of the practice and a move to new premises. However, re-notification is not necessary when x-ray equipment is changed or new equipment is obtained.

Research

- 2.11** The routine use of dental x-ray equipment for diagnostic purposes does not require authorisation under Regulation 5 of IRR99. However, the use of dental x-ray equipment for research purposes where there is no diagnostic benefit to the individual being exposed should be in accordance with the conditions of a generic authorisation granted by HSE. An RPA would be expected to be able to provide details of these conditions or they may be found on the HSE's web-site. In the unlikely event that the *Legal Person* cannot comply fully with the conditions in the generic authorisation, the *Legal Person* must apply to HSE for individual authorisation before undertaking the research.

- 2.12** In addition, IR(ME)R2000 places a number of requirements on any *Legal Person* undertaking the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes. Any *Legal Person* planning to undertake such research is strongly advised to consult an MPE to ensure compliance with the IR(ME)R2000 requirements.

Risk assessment for ionising radiations

2.13 Under both MHSWR99 and IRR99, the *Legal Person* is required to have undertaken a risk assessment for the purpose of identifying the measures needed to restrict the exposure of himself and other persons. Regulation 3(6) of MHSWR99 requires that the significant findings of the risk assessment, and the details of any group of employees identified as being especially at risk, have to be recorded if there are five or more employees. However, it is recommended that the findings of the assessment be recorded on all occasions.

2.14 Three basic provisions associated with a risk assessment are:

- (a) a risk assessment is required prior to any new work being undertaken with dental x-ray equipment;
- (b) the *Legal Person* should involve an RPA in the risk assessment and may also need to consult employees and workers' safety representatives about new measures affecting health and safety;
- (c) a risk assessment should be subject to routine review to ensure that it remains valid and up-to-date. It is recommended that routine reviews be undertaken at intervals not exceeding five years. Reviews should also be carried out whenever there are significant changes to the work activities, such as:
 - the introduction of new types of equipment (eg the first work with panoramic or cephalometric equipment, or with digital receptors);
 - significant changes to working methods;
 - the introduction of new legislation.

Conditions that would require a review should be included in the assessment.

2.15 The net effect is that *Legal Persons* setting up work with dental x-ray equipment for the first time, or setting up such work in a new practice, must undertake and record a prior risk assessment. Existing *Legal Persons* should have already undertaken an assessment as a requirement of the MHSWR99 (previously MHSWR92), in which case the assessment should be reviewed and updated to reflect the requirements of IRR99. If, for whatever reason, a risk assessment has not already been carried out, the *Legal Person* must arrange for one to be conducted at the earliest opportunity.

2.16 Guidance for conducting and reviewing a risk assessment can be found in Appendix 2 to these GNs. Attention is drawn to the need to take appropriate action in respect of any deficiencies identified by the assessment.

Dose limitation for workers and the public (excluding patients)

2.17 For the purposes of a general dental practice, the dose limits in IRR99 can be interpreted as follows:

Class of person	Annual limit of effective dose in millisievert (mSv)
Any employee aged 18 years or above	20 mSv
Trainees aged under 18 years	6 mSv
Other persons (including any person below the age of 16 years, and all members of the public)	1 mSv

Limits on equivalent dose are also specified for the lens of the eye, the skin and body extremities. These are not normally appropriate for exposure to dental x-rays, but might need to be considered in an accident or incident situation, in which case an RPA should be consulted.

2.18 Under normal circumstances, doses to staff and other persons will be very low and the above limits have little practical relevance in most surgeries. However, Regulation 8(1) of IRR99 places an overriding requirement on the *Legal Person* to ensure that radiation doses to staff and other persons are always as low as reasonably practicable (known as 'Optimisation'). It is this requirement that is the prime objective of the various sections of these GNs that address the protection of staff and other persons.

As an aid to Optimisation at the planning stage of any new facility, IRR99 suggest the setting of 'Dose Constraints'. These represent the upper level of individual dose that should not be exceeded in a well-managed practice. Where applicable, the following annual dose constraints are recommended for dental radiography:

1 mSv	for employees directly involved with the radiography (<i>operators</i>);
0.3 mSv	for employees not directly involved with the radiography and for members of the public.

A design of a new dental x-ray facility is unlikely to be considered satisfactory if the predicted annual doses exceed these dose constraints.

2.19 In addition to the above dose limits, the *Legal Person* must ensure that the dose to the fetus of any pregnant member of staff is unlikely to exceed 1 mSv during the declared term of the pregnancy. In dental practice it would be considered unusual for any member of staff to be exposed to radiation to an extent that would lead to this level of fetal dose. However, the *Legal Person* should review the work and the likely dose to ensure compliance with this restriction on dose to the fetus. In particular, in situations where the radiographic workload is high and the pregnant woman personally attends more than 100 exposures per week, an RPA should be consulted for more specific advice to ensure that the dose to the fetus will be less than 1 mSv.

Training

2.20 Under IRR99, the *Legal Person* is required to ensure that:

- (a) staff directly engaged in any aspect of radiography have received appropriate and adequate training commensurate with their duties, so that they know:
 - the risks to health created by exposure to x-rays;
 - the precautions that need to be taken;
 - the importance of complying with the medical, technical and administrative requirements of legislation (of special relevance to appointed RPSs, who should have a working knowledge of the requirements of IRR99);

- (b) other persons who are directly concerned with the radiography are given adequate information to ensure their health and safety, (eg a parent supporting a child – see paragraph 3.22);

- (c) female employees engaged in the radiography are informed of the possible risk to a fetus and of the importance of informing the *Legal Person*, in writing, if they become aware that they are pregnant.

2.21 The *Legal Person* is also advised to ensure that all non-clinical staff are provided with adequate basic information so that they are aware of the use of x-rays in the practice and of the need and the way to avoid unnecessary personal exposure.

2.22 Regulation 4(4) of IR(ME)R2000 places a responsibility on the *Legal Person* to ensure that every *IRMER practitioner* and *operator* has received adequate and appropriate training and undertakes continuing education and training after qualification. A summary of the requirements appropriate to dentistry is given in Appendix 3. An up-to-date record of training must be maintained and be available for inspection (see paragraph 5.26).

2.23 Information leaflets can provide useful support for staff training. Sources of such leaflets include NRPB and the BDA Advisory Service.

Radiation Protection File (Local Rules and *Legal Person's* Procedures)

2.24 The *Legal Person* is required to provide written 'Local Rules' if a controlled area has been designated under IRR99. These rules are intended to identify the key working instructions to ensure that exposure to staff is restricted. It is recommended that Local Rules be provided in all cases, whether or not a controlled area has been designated.

2.25 The *Legal Person* is required to provide a framework under IR(ME)R2000 for *IRMER practitioners* and *operators* to work under. These must include a number of written

'Employer's Procedures' concerning matters of patient protection. Within these GNs, these are called *Legal Person's* Procedures.

2.26 It will generally be convenient for as much as practicable of the required information to be contained in a single document, and this document will be referred to as the 'Radiation Protection File' in these GNs. Some additional information and instructions may need to appear in the QA programme and possibly in some other working instructions.

2.27 Guidance on the essential content of the 'Radiation Protection File' (including the Local Rules and *Legal Person's* Procedures) will be found in Appendix 4 to these GNs.

Duties of employees

2.28 Notwithstanding the many and varied responsibilities placed on the *Legal Person*, regulation 34 of IRR99 also places duties on employees including:

- (a) to not knowingly expose themselves or any other person to x-rays to an extent greater than is reasonably necessary for the purposes of their work;
- (b) to exercise reasonable care when working on any aspect of dental radiology;
- (c) to immediately report to the *Legal Person* whenever they have reasonable cause to believe that an incident or accident has occurred with the x-ray equipment, or that they or some other person have received an overexposure.

Administrative and procedural aspects of patient protection

Referral

2.29 When a *referrer* wishes to refer a patient for radiographic examination, sufficient clinical information must be supplied to enable the *IRMER practitioner* to decide whether the exposure is justified. A history and clinical examination of the patient is **essential** prior to any request for radiographs⁽¹⁶⁾.

2.30 In a dental practice it will be common for the *referrer* and *IRMER practitioner* to be the same person, in which case the formal exchange of clinical information is unnecessary. However, whenever the *referrer* and *IRMER practitioner* are not the same person (eg a patient is referred to another practice or hospital, or to another *IRMER practitioner* at the same practice), the *referrer* must supply the required information. It is recommended that this include previous relevant radiographs (where possible) and at least the following:

- (a) unique identification of the patient;
- (b) clinical information to justify the requested exposure;
- (c) unique identification of the referrer;
- (d) if relevant (see paragraphs 2.38 to 2.40), information on pregnancy or last menstrual period.

2.31 The *Legal Person* must always establish guidelines for referral criteria for radiographic examinations and ensure that these are available to all *referrers* even when the *IRMER practitioner* and *referrer* are the same person. When establishing such criteria, the *Legal Person* may wish to make use of the booklet published by the FGDP-RCS, 'Selection Criteria for Dental Radiography'⁽¹⁶⁾, or similar guidelines⁽¹⁷⁾.

Justification

2.32 Before an exposure can take place, it must be justified by an *IRMER practitioner* and authorised as the means of demonstrating that it has been justified. In deciding whether an individual exposure is justified the *IRMER practitioner* must give appropriate weight to:

- (a) the availability and findings of previous radiographs;
- (b) the specific objectives of the exposure in relation to the history and examination of the patient;
- (c) the total potential diagnostic benefit to the individual;
- (d) the radiation risk associated with the radiographic examination;
- (e) the efficacy, benefits and risk of available alternative techniques having the same objective but involving no, or less, exposure to ionising radiation.

For an exposure to be justified, the benefit to the patient from the diagnostic information obtained should outweigh the detriment of the exposure. The exposure would normally be expected to provide new information to aid the patient's management or prognosis.

2.33 In deciding whether an exposure is justified, the *IRMER practitioner* must take into account the clinical information supplied by the *referrer* and may also wish to refer to the booklet published by the FGDP-RCS, 'Selection Criteria for Dental Radiography'⁽¹⁶⁾, or any similar guidelines⁽¹⁷⁾.

2.34 There can be no possible justification for the routine radiography of 'new' patients prior to clinical examination. A history and clinical examination are the only acceptable means for determining that the most appropriate, and necessary, radiographic views are requested⁽¹⁶⁾.

2.35 The *Legal Person* should establish the method of authorisation. It will depend on local circumstances and may include a signature in the patient's clinical notes or the addition of an electronic signature. Whatever the method, any subsequent audit should be able to identify who made the clinical examination and who authorised any particular exposure as justified. It is not necessary to detail the reasoning behind the decision.

Medico-legal and other third-party exposures

2.36 The benefit from radiological examinations carried out to provide information for medico-legal purposes is primarily accrued by the third parties or the insurer, or is of financial rather than medical benefit to the individual examined. In view of this general lack of direct

health benefit, the need for and usefulness of such examinations should be critically examined when assessing whether they are justified. Prior to such examinations taking place, it is recommended that the patient's written consent be obtained.

- 2.37** It is recommended that such exposures only be requested by a medical/dental practitioner. This will usually be either a medical compensation tribunal doctor/dentist, or a medical/dental practitioner employed by an insurance company for the purpose of performing clinical examinations. The *Legal Person's* procedures must include a protocol for medico-legal and other exposures taken to inform a third party.

Female patients of child-bearing age

- 2.38** Regulation 6(1)(e) of IR(ME)R2000 prohibits the carrying out of a medical exposure of a female of child-bearing age without an enquiry as to whether she is pregnant, if this is relevant.
- 2.39** Such an enquiry will not normally be necessary in dental radiography, because it is only relevant if the primary x-ray beam is likely to irradiate the pelvic area. It is recognised that dental radiography is often avoided if the patient is known to be pregnant, essentially for psychological reasons. For the vast majority of dental projections the pelvic area is not irradiated and an acceptable course of action would be to explain to the pregnant patient that a dental radiograph delivers such a small dose to the fetus that the associated risk can be regarded as negligible. However, because of the emotive nature of radiography during pregnancy, the patient could be given the option of delaying the radiography.
- 2.40** If the radiographic examination is such that the pelvic area might be irradiated (eg the unlikely occurrence of a vertex occlusal projection), a proper course of action would be:
- (a) the *operator* asks the patient whether she is, or might be, pregnant and records the response;
 - (b) if there is no possibility of pregnancy, the radiographic examination can proceed;
 - (c) if the patient is definitely, or probably, pregnant, the *IRMER practitioner* should review the justification for the proposed radiographic examination and decide whether to defer the investigation until after delivery. If the examination is undertaken, the fetal dose must be kept to a minimum consistent with the diagnostic purpose. In such situations the use of a lead apron is advised, principally because of the reassurance that it provides;
 - (d) if the patient cannot exclude the possibility of pregnancy, she needs to be asked whether her menstrual period is overdue. If pregnancy cannot be excluded but her menstrual period is not overdue, the examination can proceed. If the period is overdue, the advice in paragraph (c) should be followed.

Optimisation

- 2.41** For every x-ray exposure, the *operators* must ensure that doses arising from the exposure are kept as low as reasonably practicable and consistent with the intended diagnostic purpose. This is known as ‘Optimisation’ of protection.
- 2.42** The *Legal Person* must ensure that written protocols are in place for every type of standard projection for each x-ray set and should include the exposure settings. These can appear in the Radiation Protection File (see paragraph 2.26), and it is recommended that they also be readily available adjacent to the x-ray equipment.
- 2.43** Optimisation is a process that relies heavily upon professional competence and skill. While the operating procedures and protocols, established by the *Legal Person*, provide a framework, the *operators* should still use their skill and knowledge in deciding how best to perform individual exposures.
- 2.44** Where a standard protocol is followed, exposure factors do not need to be recorded. However, for non-standard exposures, the factors relevant to the patient dose should be recorded so that, if necessary, an estimation of the dose to the patient can be made at a later date (eg following an enquiry or complaint from a patient).
- 2.45** The *Legal Person* must provide procedures to ensure that a clinical evaluation of the outcome of each exposure is carried out and recorded. If it is known prior to the exposure taking place that no clinical evaluation will occur, then the exposure is not justified and must not take place.
- 2.46** Clinical evaluation does not necessarily have to be a full radiology report, but should show that each radiograph has been evaluated and should provide enough information so that it can be subject to a later audit. For example, this information may include:
- (a) the charting of caries;
 - (b) findings relevant to the patient’s management or prognosis;
 - (c) in the case of a pre-extraction radiograph, it may be sufficient to record either ‘root form simple’ or ‘nothing abnormal diagnosed’.
- 2.47** Diagnostic Reference Levels (DRLs) are defined in IR(ME)R2000 as dose levels in radiodiagnostic practices for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. As such, they would not normally be expected to be exceeded without good reason.
- 2.48** In consultation with an MPE the *Legal Person* must adopt DRLs for local use having regard to national DRLs where available. At the time of preparing these GNs, no national DRLs for dental radiography had been formally recognised by the Department of Health. However, based on widespread national dose surveys, NRPB recommended reference dose values for

intra-oral and panoramic dental radiographs in 1999⁽¹⁸⁾. In the absence of formally recognised national DRLs, the *Legal Person* is recommended to adopt these NRPB reference dose values (or any subsequent revisions) as DRLs for local use. The representative patient doses determined at the 'acceptance test' and at each 'routine test' (see paragraph 3.18 of these GNs) can be compared with these local DRLs, and appropriate action taken based on the advice of an RPA. For example, where radiography is being carried out using doses consistently above the DRLs, a thorough review of radiographic practice must be made either to improve the current techniques or to justify their continued use.

2.49 Attainment of doses at or below the DRLs is not necessarily indicative of optimum performance; further dose reduction may still be practical. *Legal Persons* are encouraged to periodically review local patient dose data to determine whether their procedures and equipment would support the adoption of a DRL value lower than the current national DRL (or recommended reference dose).

2.50 Attention is drawn to a new concept known as 'Achievable Dose'⁽¹²⁾. This will be based on operational and technological factors and is likely to be gradually introduced to support DRLs so as to encourage practices already below current DRLs to optimise patient protection.

'Excessive' exposure of patients

2.51 An incident may arise as a result of an equipment malfunction, an *operator* error, or a failure to follow standard procedures. Where a *Legal Person* knows or has reason to believe that an incident may have occurred in which a patient has received an exposure that is much greater than intended, the *Legal Person* should consult an RPA without delay. In this context '*much greater than intended*' should be taken as greater than a certain multiple of the *intended dose*. This multiple may depend on circumstances and its magnitude should be discussed with an RPA. However, Guidance Note PM77⁽¹⁹⁾ issued by HSE suggests that for dental radiography a multiple of 20 should always be regarded as '*much greater than intended*'. The *intended dose* is the patient dose that is typical for the examination at the particular establishment.

Where there is difficulty in applying this multiple to an actual dose, it can be applied to exposure time, volume of tissue irradiated, or some other measure broadly representative of patient exposure.

2.52 The *Legal Person* shall make an immediate preliminary investigation of the incident. Unless this investigation shows beyond reasonable doubt that no such incident has occurred, the *Legal Person* is required to notify the appropriate authority. For incidents that are a result of a malfunction or defect in equipment, Regulation 32(6) of IRR99 applies and HSE is the appropriate authority. Notifications should be made to the local HSE office. For incidents that are not a result of a malfunction or defect in equipment (ie clinical errors, errors of

judgement or *operator error*) Regulation 4(5) of IR(ME)R2000 applies and the IRMER Inspectorate is the appropriate authority.

2.53 A detailed investigation must then be carried out and should be in conjunction with an RPA. The purpose of this investigation is to:

- (a) establish what happened;
- (b) identify the failure;
- (c) decide on remedial action to minimise the chance of a similar failure;
- (d) estimate the doses involved.

The report of this investigation must be retained, by the *Legal Person*, for at least 50 years.

2.54 As a matter of good practice, patients who have been exposed to a dose much greater than intended should be informed of the incident, unless it can be justified not to do so. It is a local decision on how, when and by whom the patient is notified, but the *IRMER practitioner* and referring clinician should be involved. Decisions not to inform the patient should be clearly recorded in the patient's case notes.

2.55 Patients who undergo a procedure that was not intended, as a result of mistaken identification or other procedural failure, and consequently have been exposed to a radiation dose, should be considered as having received an unintended dose. An investigation and notification to the IRMER Inspectorate is required.

2.56 The Medical Devices Regulations 1994⁽²⁰⁾ require manufacturers to report adverse incidents to the Medical Devices Agency (MDA). Also, the MDA operates a scheme to encourage users to report any adverse incident concerning medical devices. Prompt reporting allows the MDA, where necessary, to issue warnings and take appropriate action with the manufacturer. The *Legal Person* is advised to report incidents that were a result of a malfunction or defect in equipment to manufacturers so they can fulfil their legal obligations. The *Legal Person* is also advised to report all incidents to the MDA (see Appendix 7 for the address), whether attributable to an equipment defect or human error. MDA policy is that it is concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability.

Quality Assurance

2.57 Both IRR99 and IR(ME)R2000 place clear, but different, responsibilities on the *Legal Person* to establish and maintain quality assurance programmes in respect of dental radiology. The purpose of such QA is to ensure consistently adequate diagnostic information, whilst radiation doses to patients and staff are controlled to be as low as reasonably practicable.

2.58 Chapter 5 of these GNs provides the basis for a recommended QA programme.

3 Practical and procedural aspects of dental radiology

Introduction

3.1 This chapter relates to the practical and procedural aspects of dental radiology that are common to all areas of dentistry.

Controlled area[†]

3.2 To achieve effective control over routine and potential exposures to staff and other persons, it will normally be advantageous to define a 'controlled area' around the dental x-ray equipment. However, the designation of a controlled area is not simply subject to prescriptive conditions related to dose or dose rate. Paragraph 252 of Regulatory Guidance in support of IRR99⁽¹¹⁾ states that '*The main purpose of designating controlled areas is to help ensure that the measures provided under regulations 7(3) and 8(1) are effective in preventing or restricting routine and potential exposures*'. Such designation is clearly open to interpretation and might be expected to be influenced by local circumstances. Accordingly, the *Legal Person*, having consulted with an RPA, is free to reach independent conclusions as to the best means of ensuring compliance with the regulations.

3.3 In practice, the majority of *Legal Persons* might be expected to prefer to adopt a pragmatic, standard approach that is closely related to what has become routine practice under previous legislation. In consultation with an RPA the necessary control of exposure can be achieved by:

- (a) defining a controlled area around the x-ray set;
- (b) prohibiting normal access to the controlled area during radiography;
- (c) operating within procedures that are incorporated into Local Rules.

Under such an approach, the **controlled area** will only exist whilst x-rays are being generated. In deciding on the extent of the controlled area it will normally be satisfactory if the controlled area is chosen to be:

- within the primary x-ray beam until it has been sufficiently attenuated by distance or shielding, and
- within 1.5 m of the x-ray tube and the patient, in any other direction.

3.4 Since the beam is not always fully attenuated by the patient, it should be considered as extending beyond the patient until it has been intercepted by primary protective shielding, eg a brick wall.

[†]Where the term 'controlled area' is used in these GNs, it means an area as described in paragraphs 3.2 to 3.5, or an equivalent area that must be defined in the Local Rules, having consulted an RPA.

- 3.5** The definition of the controlled area in paragraph 3.3 should be adequate for a weekly workload that does not exceed 100 films on intra-oral equipment or 50 films on panoramic equipment. At this workload, it is unlikely that anyone's annual dose would exceed 1 mSv, so long as staff remain outside the controlled area during exposure. The designation of a 'Supervised Area' is then unnecessary. For workloads very different to the above, or for other reasons related to the x-ray set, an RPA may advise different criteria for defining the controlled area so long as its extent is not less than 1 m from the x-ray tube and the patient.
- 3.6** Provided that the weekly workload stated in paragraph 3.5 is not exceeded, the system of equipment checks specified in paragraph 3.18 should be sufficient to obviate the need to carry out further monitoring of radiation levels in the designated areas. These equipment checks should be supported by the ongoing QA programme so that any equipment malfunction will be quickly recognised and rectified.

Classification of staff and personal dosimetry

- 3.7** Provided the Local Rules are observed, all staff will receive an annual effective dose of considerably less than 6 mSv. Consequently, it will seldom, if ever, be necessary for staff to be designated as classified persons, under regulation 20 of IRR99. However, any staff who need to enter a controlled area must either be designated as classified persons or their entry must be subject to suitable written arrangements which may include the need to wear a personal dosimeter.
- 3.8** As staff have no routine need to enter the controlled area, personal dosimeters are not normally required. However, it is good practice to provide dosimeters if the risk assessment indicates that individual doses could exceed 1 mSv per year. In practice, this should be considered for those staff whose weekly workload exceeds 100 intra-oral or 50 panoramic films, or a pro-rata combination of each type of examination. The dosimeter wear period may be up to three months; results should be recorded and periodically discussed with an RPA to ensure that doses are optimised.

Location and installation

- 3.9** Dental radiography should be carried out in a room or a radiography area from which all persons whose presence is unnecessary are excluded while x-rays are being produced. This room or area, which may be a dental surgery or a separate examination room or a part thereof, should not be used for other work or as a passageway whilst radiography is in progress. In subsequent paragraphs this room or area is simply called the 'x-ray room'.
- 3.10** In consultation with an RPA, the x-ray room should be chosen and designed to provide safe accommodation for all persons. Either the room should be large enough to allow the operator to stand well outside the controlled area (ie preferably 2 m or more from the x-ray tube and patient, and well out of the direction of the primary x-ray beam), or a protected area should be provided for the *operator*.

The x-ray tube warning light and the patient should be visible to the *operator* throughout the radiography. It may be necessary to use mirrors or lead glass/perspex windows to achieve this. The *operator* should be able to prevent access to the controlled area, should anyone inadvertently enter the x-ray room.

- 3.11** Whether or not a protected area is provided for the *operator* depends on the equipment in use, the *operator's* position and the radiographic workload. Such a protected area would not be expected to be required if the total equipment workload does not exceed that stated in paragraph 3.8 above. Where a protected area is provided it should be sited out of the direction of the main x-ray beam and incorporate protection of not less than the equivalent of 0.5 mm of lead.
- 3.12** Control panels (where possible), exposure switches, mains isolators and power switches should be positioned outside the controlled area. It is preferable if the equipment can be isolated from the electrical mains supply without the *operator* having to enter the controlled area.
- 3.13** If more than one x-ray set is sited in any room (eg in open plan accommodation), arrangements should be made in consultation with an RPA to ensure that patients, staff and all other persons are adequately protected. It should not be possible for an *operator* either to inadvertently energise the wrong x-ray set or to accidentally irradiate persons working independently in another part of the room. In particular, when it is possible from a single location to initiate the production of x-rays from more than one x-ray tube, each tube should be fitted with a warning signal that is arranged to operate automatically whilst that tube is selected to emit x-rays.
- 3.14** Persons in areas outside the x-ray room should be adequately protected, meaning that the controlled area should not normally extend beyond the x-ray room. It is only acceptable for adjacent areas outside the room to be designated as controlled or supervised if they are inaccessible during radiography (eg a locked storeroom). It is recommended that the x-ray room be arranged so that use is made of the natural shielding of the walls, floor and ceiling of the room, where these are relatively thick or dense, eg of solid brick or concrete construction.

If the normal structural materials do not afford sufficient shielding (eg a light-weight partition wall) additional protective material such as lead or x-ray protective plaster may be needed depending on the use of the adjacent area. Intra-oral equipment should be installed so that the useful beam is directed away from any door, and away from any window if the space immediately beyond the window is occupied. Panoramic and cephalometric equipment should be installed so that windows and doors are not within the controlled area.

Room warning signs and signals

3.15 When a controlled area extends to any entrance of the x-ray room, a warning notice should be provided on the outside of the door. This notice must conform to current legal requirements⁽²¹⁾ and include the basic ionising radiation symbol. Additionally, an automatic warning light should normally be provided at the entrance to indicate when radiography is in progress. This light should be illuminated whilst the mains supply to the x-ray set is on, and the mains supply should be switched off when radiography is not imminent. The warning notice should explain the significance of the warning light and include words such as 'controlled area: do not enter when light is on'. Such a warning may be unnecessary if the *operator* is physically able to prevent access to the room whilst radiography is in progress.

Maintenance and testing

3.16 The radiation safety features of equipment must be properly maintained. Equipment cannot be considered safe, from a radiation protection point of view, unless it is in good order both mechanically and electrically. Maintenance and associated checks should be in accordance with the advice of the manufacturer, the supplier and the RPA. Automatic processors should be subject to a maintenance schedule. Additionally, attention is drawn to paragraphs 5.13 to 5.17.

3.17 Suppliers, erectors or installers of dental x-ray equipment are required, under Regulation 31(2)(c) of IRR99 and under the Medical Devices Regulations 1994⁽²⁰⁾ to provide the *Legal Person* with adequate information about the proper use, testing and maintenance of that equipment.

3.18 Dental x-ray equipment must be subject to the following tests:

- (a) a 'critical examination' by the installer, following installation;
- (b) an adequate test before the equipment is put into clinical use (the 'acceptance test');
- (c) further adequate tests at appropriate intervals ('routine tests') and after any major maintenance procedure;
- (d) at suitable intervals, measurements to assess representative patient doses.

Guidance on the content of such tests, including necessary RPA and MPE involvement, is given in Appendix 5.

It will often be convenient if the *Legal Person* is able to arrange for the 'acceptance test' to be combined with the 'critical examination'. The 'acceptance test' should include measurements to assess representative patient doses.

It is recommended that routine tests normally be carried out at intervals not exceeding three years. However, annual testing is recommended if:

- (a) assessed representative patient doses exceed the DRL;
- (b) image quality analysis indicates a failure to meet the targets specified in Table 5.2 (Chapter 5);
- (c) the QA programme identifies some other significant performance weakness.

In any of these events, it is recommended that the equipment be subsequently tested at annual intervals until there is full confidence that acceptable performance is being maintained.

It will be adequate for representative patient doses to be assessed as a part of each routine test, provided that the QA programme is able to confirm acceptable ongoing quality of radiographs.

3.19 Electrical and mechanical faults could give rise to inadvertent radiation exposure, for example, a faulty cable to a hand switch or a failure or malfunction of the rotational movement mechanisms on panoramic equipment. It is expected that these kinds of faults will be identified and rectified by the *Legal Person's* overall programme of managing work equipment safely. For further advice, see Safe Use of Work Equipment, ACoP and guidance on the Provision and Use of Work Equipment Regulations 1998⁽¹⁰⁾.

3.20 A record of maintenance, including any defects found and their repair, should be kept for each item of x-ray equipment and relevant auxiliary equipment. Following maintenance, the service engineer should provide a written report prior to handing the equipment back for clinical use. This should detail any changes that may affect radiation dose (to patient or staff) or image quality. The RPA and MPE should be consulted as necessary. When a maintenance log is provided, there is a legal duty to keep it up to date.

General procedures

3.21 The tube housing should never be held by hand during an exposure. The *operator* should stand well outside the controlled area and, preferably, at least 2 m away from the x-ray tube and patient, making use of the full length of cable to the exposure switch. Where a protective panel is provided the *operator* should stand behind it.

3.22 If it is necessary to provide assistance by supporting a handicapped patient or a child during radiography, a risk assessment should be undertaken in consultation with an RPA. Matters to consider include the following:

- (a) the need to avoid the same member of staff regularly providing assistance;
- (b) whether a parent or other accompanying adult can provide the assistance;

- (c) the information that needs to be provided for any such parent or accompanying adult to ensure that they are aware of the risks involved and are willing to incur the small exposure that they will receive;
- (d) the provision of a lead apron for the assisting adult, who should nevertheless be instructed to keep all parts of his or her body out of the main x-ray beam;
- (e) the assisting adult should not be a pregnant woman;
- (f) the method to use to demonstrate that the dose to the assisting adult has been restricted – in this respect personal monitoring should be considered but will not normally be necessary unless an individual member of staff is likely to provide assistance on more than 25 occasions in a year;
- (g) the provision of suitable written arrangements to specify the acceptable conditions under which such assistance can be given.

A record must be kept for at least two years of the results of any personal monitoring, and made available on request to the person monitored. It is recommended that records should be maintained of all occasions when this form of assistance has been provided. The records should be designed to enable periodic audits to be made to demonstrate that the advice of the RPA has been followed.

- 3.23** Where equipment provides a choice of beam or field sizes, the smallest reasonably practicable size should be used consistent with the radiographic procedure.
- 3.24** The *operator* should check that the exposure warning light and, where provided, any audible warning signal, operates at each exposure and ceases at the end of the intended exposure. If the exposure does not appear to have terminated as intended, the unit needs to be immediately disconnected from the mains electricity supply. An RPA should be consulted and a preliminary investigation must be undertaken to ascertain whether the incident warrants further investigation and possible reporting (see paragraphs 2.51 to 2.56).
- 3.25** If there is reason to think that the exposure control is defective, the exposure warning does not operate or that there may be some other fault (eg signs of damage, excessive x-ray tube temperature), the equipment should be disconnected from the supply and not used again until it has been checked and repaired by a service engineer.
- 3.26** The exposure settings should be chosen and checked by the *operator* on each occasion before an examination is made. This is especially important where available options necessitate the use of different exposure settings (eg to make allowance for the use of a long or short cone, variable kV and mA settings, different film speeds or exposure programmes).

Detectors, processing and viewing

Film

- 3.27** For intra-oral radiography, the fastest available films consistent with satisfactory diagnostic results should be used. Intra-oral films of ISO speed group E, or faster, are preferred. The use of 'instant process films' should be limited to specific essential situations, (eg during surgery or endodontics). In situations where 'rapid images' are routinely required, conventional film with rapid processing chemistry will generally give better results than instant process films.
- 3.28** For panoramic, cephalometric or extra-oral radiography, the fastest available film and intensifying screen combination consistent with satisfactory diagnostic results should be used. The speed of the system should be at least 400. The light sensitivity of the film should be correctly matched with the intensifying screens. The condition and effectiveness of the screens should be confirmed at regular intervals as part of the QA procedures. Provided that screens are handled carefully during routine use, cleaning should only be required infrequently. When cleaning is necessary it should be in accordance with the manufacturer's instructions.
- 3.29** Strict attention should be paid to correct and consistent film processing so as to produce good quality radiographs and avoid the necessity for examinations to be repeated. Where automatic processing is used, the processor should be properly cleaned and maintained. In the case of manual processing, the temperature of the developer should be checked prior to film processing and the development time adjusted in accordance with the film manufacturer's instructions. The developer should be changed at regular intervals in accordance with the manufacturer's instructions.
- 3.30** In order to extract full diagnostic information from the films it is essential to have dedicated viewing facilities. A specially designed light-box should be installed in an area where the ambient lighting can be adjusted to appropriate levels. Suitable film masking should be used to optimise the viewing conditions by cutting out stray light. For viewing dense areas of a radiograph the incorporation of a high intensity light source in the light-box is recommended. The provision of magnification by a factor of two would be beneficial.

Digital detectors

- 3.31** In selecting digital equipment, it is necessary to ensure that the chosen system offers the sensor sizes that are clinically required. Sensor sizes should be available in a range that is comparable with dental film.
- 3.32** The sensitivity of the detector system has to be compatible with the x-ray set(s) for which it is to be used. Ideally the x-ray set should have an effectively constant operating potential with the ability to select sufficiently low exposure settings to enable the full extent of available dose savings to be realised.

3.33 Exposure settings should be reduced to the minimum compatible with the diagnostic quality of the image.

3.34 Because of the ease with which radiographs can be retaken, it is essential to ensure that all retakes are properly justified, recorded and included in QA statistics.

Procedures specific to intra-oral radiography

3.35 This section relates to the use of intra-oral films and digital detectors wholly (periapical or bitewing) or partly (occlusal) in the mouth, and also to the use of extra-oral films obtained with similar x-ray equipment.

3.36 Whenever practicable, techniques using film holders incorporating beam-aiming devices should be adopted for bitewing and periapical radiography. If rectangular collimation is being used, a beam aiming device is essential for accurate alignment with the intra-oral film. Attention is drawn to the probable need for additional *operator* training in the use of film holders when moving from circular to rectangular collimation.

3.37 Open ended beam collimators/directors should conform to the recommendations of paragraph 4.13. When a choice of beam collimators/directors is provided, the one most suited to the technique to be employed should be fitted, ideally just covering the film or image detector. The open end of the collimator/director should be placed as close as possible to the patient's head to minimise the size of the incident x-ray beam. If it is desired to use a longer focus-to-skin distance (FSD), a longer collimator/director should be employed.

3.38 The dental film or digital detector should only be held by the patient when it cannot otherwise be kept in position. It should not normally be hand-held by anyone else. Exceptionally it may be held by someone other than the patient using a pair of forceps, or other appropriate holder, to avoid direct irradiation of the fingers, for example, when a child or a handicapped person cannot hold it themselves. In such cases advice should be sought from an RPA and will be based on similar principles to that contained in paragraph 3.22 .

3.39 Extra-oral and vertex occlusal views should always be taken with cassettes incorporating appropriately matched film and intensifying screen combinations. It is recommended that a left and/or right marker be used on the cassette to confirm which side of the patient has been imaged.

Procedures specific to panoramic radiography

3.40 Where panoramic equipment features a cephalometric mode of operation, a check should be made before every exposure to ensure that the correct collimator is in place for

panoramic operation. (Some designs provide an interlock to ensure that this is the case). Additionally, where the equipment features a number of different rotational modes (eg TMJ mode), a check should be made before every exposure to ensure that the correct mode has been selected.

- 3.41** If the rotational movement fails to start or stops before the full arc is covered, the exposure switch should be released immediately to avoid high localised exposure of the patient. The reason for any such failure should be investigated, and any faults rectified by an engineer before the equipment is used again for clinical purposes.
- 3.42** It is no longer acceptable to undertake panoramic radiography using an x-ray tube placed inside the patient's mouth.

Procedures specific to cephalometry

- 3.43** To minimise magnification effects, the focus-to-film distance should be greater than 1m and ideally within the range 1.5 to 1.8 m.
- 3.44** The patient should be positioned in relation to the x-ray field by means of a cephalostat. The *operator* should use film/cassette position marks incorporated on the cephalostat to ensure the film/cassette is correctly aligned in relation to the selected collimator.
- 3.45** An intra-oral dental x-ray set should not be used for cephalometry, other than with specially designed ancillary equipment. Even then, the ongoing suitability of the equipment for cephalometry should be confirmed with an RPA and/or MPE.

Protective clothing

- 3.46** There is no justification for the routine use of lead aprons for patients in dental radiography. Thyroid collars should be used in those few cases where the thyroid may be in the primary beam, based on advice from an MPE. Lead aprons do not protect against radiation scattered internally within the body, and only provide a practicable degree of protection in the case of the infrequently used vertex occlusal projection. Even in this case, the use of the lead apron could only be regarded as prudent for a female patient who is, or may be, pregnant (see also paragraphs 2.38 to 2.40).
- 3.47** Protective aprons, having a lead equivalence of not less than 0.25 mm, should be provided for any adult who provides assistance by supporting a patient (see paragraph 3.22).
- 3.48** When a lead apron is provided, it must be correctly stored (eg over a suitable hanger) and not folded. Its condition must be routinely checked including a visual inspection at annual intervals.

4 Equipment aspects of dental radiology

Introduction

4.1 This chapter relates to the equipment aspects of dental radiology that are common to all areas of dentistry.

General

4.2 Dental x-ray equipment should be designed, constructed and installed to be in compliance with recognised British, European or international standards of construction, thereby enabling the recommendations in this chapter to be met. Medical devices placed on the market in the European Union must meet the relevant essential requirements for safety and performance of the Medical Devices Directive 1993⁽²²⁾, which was transposed into UK law by the Medical Devices Regulations 1994⁽²⁰⁾.

4.3 Equipment that is CE marked would be expected to comply with the relevant standards, and the *Legal Person* should ensure that proposed new equipment bears the appropriate CE marking.

X-ray source assembly

4.4 Every intra-oral dental x-ray source assembly (comprising an x-ray tube, x-ray tube housing and a beam limiting device) should be constructed so that, at every rating specified by the manufacturer, the air kerma from the leakage radiation at a distance from the focal spot of 1 m, averaged over an area not exceeding 100 cm², does not exceed 0.25 mGy in one hour. For other dental x-ray source assemblies, the equivalent leakage radiation should not exceed 1 mGy in one hour⁽²³⁾.

4.5 The x-ray tube head should be marked to identify the nominal focal spot position⁽²⁴⁾.

Beam filtration

4.6 The total filtration of the beam (made up of the inherent filtration and any added filtration) should be equivalent to not less than the following⁽²³⁾:

- (a) 1.5 mm aluminium for x-ray tube voltages up to and including 70 kV;
- (b) 2.5 mm aluminium, of which 1.5 mm should be permanent, for x-ray tube voltages above 70 kV.

- 4.7** The advice of a MPE should be sought if considering the use of a dose reduction or optimisation strategy incorporating filtration levels significantly greater than those in paragraph 4.6.

The use of filtration significantly greater than these values will be undesirable if it creates the need for exposure times greater than one second for an intra-oral examination.

- 4.8** The value of the inherent filtration and any added filtration should be marked clearly on the tube housing in millimetre aluminium equivalent⁽²⁹⁾. Every added filter should also be clearly marked with its filtration in aluminium equivalent. Where materials other than aluminium have been used as filters, the x-ray tube should be clearly marked with the chemical symbol and thickness in millimetres of the filter or marked with the equivalent filtration in millimetres of aluminium.

X-ray tube operating parameters

- 4.9** Equipment for dental radiography should incorporate adequate provision for the adjustment of exposure factors to allow for the range of views, patient size, and modern film/screen combinations that are routinely encountered (ie a suitable range and adjustment of kV, mA and time should be available). Medium frequency dental x-ray generators with an effectively constant potential (DC) output are preferred to one and two pulse (AC) generators.
- 4.10** For intra-oral radiography the nominal tube potential should not be lower than 50 kV. New equipment should operate within the range 60 to 70 kV.
- 4.11** For panoramic and cephalometric radiography with manual control, a range of tube potential settings should be available, preferably from 60 to 90 kV. There should be provision for the selection of a range of tube currents so that full advantage can be taken of the sensitivity of modern film/screen combinations.
- 4.12** All equipment should operate within $\pm 10\%$ of the stated or selected tube potential. It is recommended that intra-oral sets operating at less than 50 kV be withdrawn from use as soon as is reasonably practicable. Any sets still in use that operate at less than 45 kV should be immediately withdrawn from use.

It is further recommended that, whatever their operational tube potential, sets that cannot attain representative patient doses at or below the DRL (see paragraphs 2.47 to 2.49) be withdrawn from use as soon as is reasonably practicable. Any sets still in use that deliver representative patient doses in excess of double the DRL should be immediately withdrawn from use.

The continued use of such equipment cannot be regarded as complying with the requirement, of regulation 32(1) of IRR99, that equipment be capable of keeping patient doses as low as reasonably practicable.

Beam size, beam alignment, film holders and distance control

Intra-oral radiography

- 4.13** It is recommended that rectangular collimation be provided on new equipment and be retro-fitted to existing equipment at the earliest opportunity. Rectangular collimation should be combined with beam-aiming devices and film holders, since this not only reduces patient dose but will also improve the diagnostic quality of radiographs and reduce the proportion of rejected films. Rectangular collimators should be designed so that the beam size at the end of the collimator does not exceed 40 by 50 mm (ie does not overlap the dimensions of the standard ISO film size 2 by more than 5 mm at any edge) and it would be preferable for this to be further reduced such that it does not exceed 35 by 45 mm (ie no more than a 2.5 mm overlap at any edge).

Where circular x-ray beams continue to be used, the beam diameter should not exceed 60 mm at the end of the beam collimator/director, with a maximum tolerable error of +3 mm. It is stressed that beam diameters less than this, and rectangular collimation, will reduce patient dose.

Beam collimators/directors should be open ended and provide a minimum focus-to-skin distance (FSD) of 200 mm for equipment operating at 60 kV or greater and an FSD of at least 100 mm for equipment operating at below 60 kV⁽²³⁾. Where x-ray output permits, FSDs larger than this can produce radiographs with improved geometry and lower patient dose.

Panoramic radiography

- 4.14** Equipment needs to be provided with patient positioning aids, which need to incorporate the use of the light beams if they are to be effective.

Field limitation can significantly reduce patient exposure when specific diagnostic information is required. New equipment should be provided with automatic selection of beam limitation, although manual selection is acceptable. All primary beam defining slits (more than one may be selectable) should be accurately aligned with the receiving slit.

The beam height at the receiving slit or secondary collimator should be restricted (automatically or manually) to no greater than that required to expose the area of diagnostic interest and certainly no greater than the film or detector in use (normally 120 mm or 150 mm). The beam width should be no greater than 5 mm.

Cephalometry

- 4.15** Equipment needs to be able to ensure the precise alignment of x-ray beam, film cassette and patient. A light beam diaphragm, or other suitable means, should be provided so that the beam can be accurately collimated to include only the diagnostically relevant area⁽²⁵⁾.

To facilitate the imaging of soft tissues, a wedge filter should be provided at the x-ray tube head, in preference to one at the film cassette.

The use of intra-oral equipment adapted for cephalometry should be positively discouraged. However, where such equipment continues in use it should do so only with the specific approval of an RPA or MPE.

Warning signals

- 4.16** There should be a light on the control panel to show that the mains is switched on. This indicates a state of readiness to emit radiation.
- 4.17** All dental equipment should be fitted with a light that gives a clear and visible indication to the *operator* that an exposure is taking place. The light should be triggered by conditions associated uniquely with the commencement and termination of the emission of radiation, but arranged to be seen irrespective of the length of the exposure duration. Audible warnings, provided in addition to the visual warning, should be triggered by the same conditions.

Exposure control

- 4.18** The exposure should be terminated automatically when a predetermined condition, such as the preset time, has been attained. Systems allowing automatic exposure control, for example on some panoramic or cephalometric systems and with some digital detectors, should incorporate a suitable guard timer circuit to prevent excessive exposure in the event of failure of the automatic means. It is recommended that such automatic exposure control systems be always arranged to provide a post-exposure indication of the mAs or time given.
- 4.19** Exposure switches on all dental x-ray equipment should be arranged so that an exposure occurs only while continuous pressure is maintained on the switch and terminates if pressure is released. To guard against failure of the control circuitry, an additional means of termination should be provided which is independent of the normal means. The release of the exposure switch may be regarded as the additional means provided that this action overrides the timer. Exposure switches relying on remote control to initiate the exposure should incorporate all the safety features of conventional exposure switches, with regard to exposure control and release.

- 4.20** Exposure switches should be designed to prevent inadvertent production of x-rays. If re-setting is automatic, it should be ensured that pressure on the switch has to be released completely before the next exposure can be made.
- 4.21** The exposure switch should be arranged so that the *operator* can remain outside the controlled area and, preferably, at least 2 m away from the tube and the patient during exposure. It should be located or arranged so that inadvertent or unauthorised use is not normally possible.
- 4.22** The x-ray output from intra-oral x-ray equipment should be able to be adjusted such that dental films to be used can be exposed correctly and consistently. This requires the provision of a suitable film speed control and/or suitably fine adjustment of appropriate exposure time settings.
- 4.23** When purchasing new panoramic equipment it is recommended that equipment be chosen which is designed to abort the exposure automatically on sensing a failure or interruption of rotational movement, thereby avoiding an unnecessary and high localised skin dose to the patient. Additionally, the immediate release of the exposure switch should also abort the exposure. When an exposure is interrupted the unit should be unable to restart from the interrupt position.

5 Quality assurance in dental radiology

Introduction

- 5.1** The purpose of Quality Assurance (QA) in dental radiology is to ensure consistently adequate diagnostic information, whilst radiation doses are controlled to be as low as reasonably practicable. The QA programme will need to take account of relevant statutory requirements and this will determine many of the operational objectives.
- 5.2** A well-designed programme should be comprehensive but inexpensive to operate and maintain. The standards should be well researched but once laid down would be expected to require only infrequent verification or modification. The procedures should amount to little more than 'written down common sense' and should in fact contribute to the overall efficiency of operation by being well structured. Formal records will need to be maintained and checked; this is an essential feature of QA.

QA programme

- 5.3** A basic principle of quality assurance is that, within the overall QA programme, all necessary procedures be laid down in writing. In particular, the following are recommended:
- (a) implementation should be the responsibility of a named person (often a senior partner);
 - (b) the frequency of operations should be defined;
 - (c) the content of the essential supporting records should be defined, as should the frequency for the formal checking of such records.
- 5.4** The essential procedures within a programme suited to dental radiology will relate to:
- (a) image quality;
 - (b) patient dose and x-ray equipment;
 - (c) darkroom, films and processing;
 - (d) training;
 - (e) audits.
- 5.5** Each of the essential procedures is considered in more detail in this chapter.

QA procedures for image quality

Image quality

- 5.6** Since a principal objective of the QA programme is to ensure the production of good diagnostic quality radiographs, it is vital to monitor image quality on a regular basis. It is recommended that a simple, subjective image quality rating system be used for dental radiographs, as described in Table 5.1.

Table 5.1 Subjective quality rating of radiographs⁽²⁶⁾

Rating	Quality	Basis
1	Excellent	No errors of patient preparation, exposure, positioning, processing or film handling
2	Diagnostically acceptable	Some errors of patient preparation, exposure, positioning, processing or film handling, but which do not detract from the diagnostic utility of the radiograph
3	Unacceptable	Errors of patient preparation, exposure, positioning, processing, or film handling, which render the radiograph diagnostically unacceptable

- 5.7** Based on these quality ratings, performance targets can be set. Suitable targets are recommended in Table 5.2 and practices should aim to achieve these within three years of the implementation of the QA programme. Table 5.2 includes 'interim targets' that should be regarded as the minimum achievable standard in the shorter term.

Table 5.2 Minimum targets for radiographic quality⁽²⁶⁾

Rating	Percentage of radiographs taken	
	Target	Interim target
1	Not less than 70%	Not less than 50%
2	Not greater than 20%	Not greater than 40%
3	Not greater than 10%	Not greater than 10%

- 5.8** The QA programme should incorporate a clearly defined regime to ensure that image quality is rated and the results analysed so as to permit comparison with the targets in Table 5.2. Two alternative approaches are suggested:
- a prospective evaluation whereby image quality ratings are assigned and recorded for all radiographs as they are being viewed. This would be followed by an analysis of results and it is recommended that the intervals between analyses should not exceed six months;
 - a retrospective evaluation whereby a suitably representative sample of radiographs is drawn from clinical records at regular intervals, the image quality ratings are assigned and recorded, and the results analysed. It is recommended that this should be undertaken at intervals that do not exceed six months.

- 5.9** A record of each analysis of the results of image quality should be kept together with a record of any actions taken in response to the analysis. In particular, corrective action should be taken in cases where the appropriate performance targets are not being achieved.
- 5.10** In addition to the above formal analyses, it is recommended that day-to-day surveillance of image quality be maintained. This can be simply and economically checked by keeping good quality reference radiographs available on the viewing screen and by comparing the quality of every radiograph with these 'standards'. Any significant deterioration in quality should be investigated. Care is required to ensure that chosen reference radiographs are replaced before ageing causes significant deterioration in their quality.

Unacceptable radiographs

- 5.11** A further important quality assurance tool is an analysis of unacceptable radiographs. Whenever a radiograph is given a quality rating of 3 (ie the necessary diagnostic information could not be obtained) the reason should be recorded. This record should be made whatever the cause of the problem, and include:
- (a) the date;
 - (b) nature of the deficiency;
 - (c) known or suspected cause of this deficiency;
 - (d) number of repeat radiographs (if taken).
- 5.12** Regular analysis of such records is an invaluable aid for identifying a range of problems that would otherwise cause unnecessary radiation exposure of patients and staff. It can indicate, for example, a need for equipment maintenance, improvements in radiographic technique or improved staff training.

QA procedures for patient dose and x-ray equipment

- 5.13** Another main objective of a QA programme is to ensure that radiation doses are kept as low as reasonably practicable. It is, therefore, necessary to monitor patient doses on a regular basis. Patient doses cannot be maintained as low as reasonably practicable unless the x-ray equipment complies with recommended standards. Appropriate tests of all relevant aspects of equipment performance and evaluations of patient dose should be made in accordance with paragraphs 2.48 and 3.18.
- 5.14** If results indicate that representative doses to patients are consistently above the DRL, a thorough review of radiographic practice must be made either to improve, or to justify keeping, the current techniques.
- 5.15** For all tests, a formal written report should be obtained which describes the checks made, the results obtained and any consequent actions. An equipment log should be maintained

to record the results of all such checks in chronological order and this log should incorporate details of any routine or special maintenance on the x-ray equipment.

- 5.16** Routine surveillance should also include day-to-day checks of important features that affect radiation protection, such as correct functioning of warning lights and audible alarms, correct operation of safety devices and satisfactory performance of the counterbalance for maintaining the position of the x-ray tube. It is recommended that the equipment log include a periodic record (six monthly intervals recommended) to confirm that such checks have been performed.
- 5.17** Regulation 10 of IR(ME)R2000 requires that an up-to-date inventory of each item of x-ray equipment shall be maintained, and be available, at each practice and shall contain:
- (a) name of manufacturer;
 - (b) model number;
 - (c) serial number or other unique identifier;
 - (d) year of manufacture;
 - (e) year of installation.

QA procedures for the darkrooms, desktop processing units, films and processing

Darkrooms and desktop processing units

- 5.18** Routine checks should be made to ensure that darkrooms remain light-tight and that safelights do not produce fogging of films. It is recommended that such checks be made at intervals not exceeding 12 months, and immediately following any alteration or maintenance to the safelights or to the light proofing of the room. All results should be recorded in a log. Desktop processing units should be similarly checked for light-tightness and the results recorded.

Films and processing

- 5.19** Inadequate processing always compromises diagnostic information. The QA standards will be laid down by the suppliers of the films, processing solutions, and processing equipment and will include:
- (a) film speed, expiry date and recommended storage conditions;
 - (b) processing conditions (times and temperatures);
 - (c) changing frequency for processing solutions;
 - (d) cleaning instructions for automatic processors.

- 5.20** The QA procedures should ensure that these standards are strictly adhered to by means of the following:
- (a) records and/or procedures to control film stock;
 - (b) records to control and validate the chemical changes;
 - (c) cleaning procedures for automatic processors.
- 5.21** The overall performance of the processing also needs to be monitored. One of the simplest ways of achieving this is with the use of a test-object such as a step-wedge. This test-object is routinely radiographed, always using the same standard exposure parameters. A simple visual comparison between the resultant image and a reference film can detect variations in processing quality before they affect patient films. It is recommended that a suitable check be made after every change of processing solutions to ensure that conditions are satisfactory before patients' films are processed. More frequent checks, in some cases daily, may be appropriate where there is a need to closely monitor film processing (eg when the image quality procedures described in paragraphs 5.6 to 5.12 have identified deficiencies).
- 5.22** For large practices with a very high radiographic workload, more elaborate procedures (involving the use of sensitometry and densitometry equipment) may be appropriate, based on the advice of an RPA or MPE.

QA of working procedures

Radiation Protection File (Local Rules and Legal Person's Procedures)

- 5.23** The provision of Local Rules and Legal Person's Procedures is a legal requirement as described in paragraphs 2.24 to 2.27, where it is suggested that they be combined into a single document known as the 'Radiation Protection File'. This Radiation Protection File can contain the procedural and operational elements that are essential to the safe use of x-ray equipment and as such will contain much of what is relevant to the maintenance of good standards in quality assurance (see Appendix 4).

Operational procedures

- 5.24** Written operational procedures should be provided for all actions that indirectly affect radiation safety and diagnostic quality, ie actions not directly linked to the use of the x-ray equipment. An example would be procedures for the correct preparation and subsequent use of processing chemicals.

Procedures log

- 5.25** The QA programme should include the maintenance of a procedures log to record the existence of appropriate Local Rules, *Legal Person's* Procedures and operational procedures, together with a record of each occasion on which they are reviewed or modified. It is recommended that such reviews be undertaken at intervals not exceeding 12 months.

QA procedures for training

5.26 *IRMER practitioners and operators* must have received appropriate training to at least the standards implied by paragraph 2.22 and Appendix 3. The QA programme should incorporate a register of all staff involved with any aspect of the radiology and include the following information:

- (a) name;
- (b) responsibility;
- (c) date and nature of training received;
- (d) recommended date for a review of training needs.

5.27 The training register should incorporate details of the training provided for staff under IRR99, and *Legal Persons* are also advised to incorporate details of the information and instruction that is provided.

QA audits

5.28 Each procedure within the QA programme will include a requirement for records to be made by the responsible person at varying intervals. In addition, the person with overall responsibility for the QA programme should check the full programme at intervals not exceeding 12 months. This is an essential feature of demonstrating effective implementation of the programme.

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

- (a) the QA programme and associated records;
- (b) the justification and authorisation of radiographs (see paragraphs 2.32 to 2.35 of these GNs);
- (c) the clinical evaluation of radiographs (see paragraphs 2.45 and 2.46 of these GNs).

Any such Clinical Audit or Peer Review should be carried out in accordance with the appropriate national arrangements⁽²⁷⁾.

Appendix 1 Particulars to be provided in a notification of specified work under Regulation 6(2) OF IRR99

Table A1 Example of a form of notification, under Regulation 6(2) of IRR99, appropriate for most dental practices

NOTIFICATION OF SPECIFIED WORK UNDER REGULATION 6(2) OF IRR99 USE OF DENTAL X-RAY EQUIPMENT	
(a) Name of employer: _____	
Address of employer: _____	(b) Address of premises where dental radiography is undertaken: _____
Employer's tel no: _____	Tel no of premises: _____
Employer's fax no: _____	Fax no of premises: _____
Employer's e-mail address: _____	e-mail address of premises: _____
(c) Business of employer: <i>Dentistry</i>	
(d) Category of the source of ionising radiation: <i>Electrical equipment : dental x-ray equipment</i>	
(e) Whether the x-ray equipment will be used at premises other than that given at (b) above: <i>No</i>	
(f) Date of commencement of dental radiography:	
Date of this notification:	
Signed:	
Position:	

NOTES

- (1) In the context of section (d), notification would be in respect of 'Electrical equipment : dental x-ray equipment'. There would then be no need to notify HSE when additional x-ray sets were purchased or when changes were made either to the x-ray equipment or the radiographic technique.
- (2) The notification must be sent to the local HSE office 28 days before starting work with the x-ray equipment. Alternatively, the information contained in the form can be sent to HSE by fax or e-mail.

Appendix 2 Matters relevant to a risk assessment in pursuance of Regulation 7(1) OF IRR99

A2.1 A risk assessment is a tool to assist the Legal Person in deciding on the most appropriate measures necessary to restrict exposure. To perform a risk assessment, HSE recommends a five step approach as follows:

- (a) identify the hazards (ie routine and accidental exposure to x-rays);
- (b) decide who might be harmed and how they might be affected;
- (c) evaluate the risks and decide whether existing precautions are adequate or whether more precautions need to be taken – implement additional precautions, if needed;
- (d) record the findings of the risk assessment;
- (e) review the risk assessment and revise it, if necessary.

A2.2 In relation to the use of dental x-ray equipment, it is recommended that the risk assessment include consideration of the factors listed below.

Factor to be considered	Relevant Regulation in IRR99	Relevant paragraph(s) in these GNs
Radiation doses to staff and members of the public to be kept as low as reasonably practicable. Set dose investigation level	8	2.17 to 2.19 for dose limitation and Appendix 4 (paragraph A4.12) for dose investigation level. Otherwise this is the main thrust of the whole of these GNs
Equipment to be properly maintained, examined and tested in accordance with manufacturer's advice	10	3.16 to 3.20
Annual doses to employees must not exceed 20 mSv	11	2.17
Contingency plans to be included in Local Rules to cover potential accident or incident situations	12	Appendix 4 (paragraphs A4.4 and A4.8 to A4.11)
RPA to be consulted and appointed in writing	13	2.7
Suitable and sufficient information, instruction and training provided for all staff and adequate information given to members of the public who become involved in the radiography	14	2.20, 2.21 and 2.23
Need for controlled and supervised areas considered and appropriate action taken	16 and 18	3.2 to 3.6
Appropriate Local Rules provided and implemented	17 (1 to 3)	2.24 and 2.27, and Appendix 4
RPS(s) appointed	17 (4)	2.3
Need for personal dosimetry and record keeping considered	21	3.7 and 3.8

Factor to be considered	Relevant Regulation in IRR99	Relevant paragraph(s) in these GNs
New equipment 'critically examined' by installer	31 (2)	3.18 and Appendix 5
Equipment capable of keeping doses to patients as low as reasonably practicable	32 (1)	Chapter 4
Suitable QA programme in place, implemented and audited	32 (3)	2.57 and 2.58, and Chapter 5
Equipment subject to adequate testing	32 (4)	3.18 and Appendix 5
Employees exercise reasonable care	34	2.28

Appendix 3 Adequate training requirements under IR(ME)R2000

A3.1 Regulation 4(4) of IR(ME)R2000 places responsibility on the *Legal Person* to ensure that every IRMER *practitioner* and *operator* has received adequate training and undertakes continuing education and training after qualification. The detailed requirements are found in Regulation 11 and Schedule 2.

Adequate training

A3.2 IRMER *practitioners* and *operators* must have received adequate training. Appropriate standards for adequate training are recommended in this appendix. If assessment shows that training is inadequate, arrangements must be made for the IRMER *practitioner* and *operator* to receive the appropriate education and training. This may require self-assessment when the IRMER *practitioner* is also the *Legal Person*.

A3.3 Adequate training for an IRMER *practitioner* comprises:

- (a) for UK graduates, an undergraduate degree conforming to the requirements for the undergraduate dental curriculum in dental radiology and imaging⁽²⁸⁾ and the core curriculum in dental radiography and radiology for undergraduate dental students⁽²⁶⁾;
- (b) for non-UK graduates, the *Legal Person* should establish whether the IRMER *practitioner's* undergraduate degree matches the above requirements. Where the IRMER *practitioner* is also the *Legal Person* he or she should seek the advice of the Dental Practice Adviser and/or the Postgraduate Dental Dean.

A3.4 Adequate training for operators needs to address two groups of operators:

- (a) *Operators whose duties include selecting exposure parameters and/or positioning the film the patient and the tube head*
 - Dental practitioners should fulfil the requirements of A3.3 above.
 - Dental nurses should possess a Certificate in Dental Radiography, conforming to the syllabus prescribed by the College of Radiographers⁽²⁹⁾.
 - Dental hygienists and therapists should have received an equivalent level of training to that for dental nurses.

However, as an interim measure dental nurses who were competently undertaking radiography prior to 13 May 2000 and had only received 'Core of Knowledge'⁽³⁰⁾ training may continue to undertake radiography until 12 May 2005, by which time they should have obtained the Certificate of Dental Radiography. The *Legal Person* must document the training and relevant experience of all nurses to which this interim measure applies.

All other dental nurses should obtain the Certificate in Dental Radiography before undertaking radiography.

(b) Other operators

Dental nurses (and any other PCDs) whose duties include film processing and quality assurance should preferably possess the Certificate in Dental Nursing (or the equivalent). Failing this they must have received adequate and documented training, specific to the tasks that they undertake, and this training may be provided 'in-house'.

Dental nurses (and any other PCDs) who 'press the exposure button' as part of a patient exposure that has been physically set up by an adequately trained *operator*, may only do so in the continued presence, and under the direct supervision, of that *operator*. They must have received documented instruction appropriate to this task.

Continuing education and training

A3.5 Continuing education and training in all aspects of dental radiology must be part of *IRMER practitioners'* and *operators'* life-long learning.

A3.6 *IRMER practitioners*, together with *operators*, whose duties include radiography, must update their knowledge of and skills in intra-oral and panoramic radiology, as appropriate. This is especially important when installing panoramic equipment or digital imaging devices for the first time, and when implementing new techniques such as the paralleling technique. It is equally relevant if the QA programme identifies serious or persistent deficiencies in image quality, arising out of the procedures recommended at paragraphs 5.6 to 5.12. This continuing professional development (CPD) can include a mixture of Verifiable CPD and General CPD. Within the five-yearly 250 hour recertification cycle, an average practitioner would be expected to devote at least 5% of the hours to radiology and radiation protection.

A3.7 Practitioners are recommended to attend formal courses covering all aspects of radiation protection as part of their five-yearly recertification cycle. Such courses would normally be expected to provide at least five hours of Verifiable CPD. Postgraduate dental deans therefore need to ensure that such courses are offered on a regular basis. Appropriate courses would be expected to cover:

- (a) the principles of radiation physics;
- (b) risks of ionising radiation;
- (c) radiation doses in dental radiography;
- (d) factors affecting doses in dental radiography;
- (e) the principles of radiation protection;
- (f) statutory requirements;
- (g) selection criteria;
- (h) quality assurance.

A3.8 Operators whose duties include radiography are recommended to attend a continuing education and training course every five years. Appropriate courses would be expected to cover:

- (a) the principles of radiation physics;
- (b) risks of ionising radiation;
- (c) radiation doses in dental radiography;
- (d) factors affecting dose in dental radiography;
- (e) the principles of radiation protection;
- (f) statutory requirements;
- (g) quality assurance.

Appendix 4 Essential content of radiation protection file

- A4.1** As explained in paragraphs 2.24 to 2.27, Local Rules that derive from IRR99 are recommended for all practices. *Legal Person's* Procedures are required under IR(ME)R2000. It is suggested as much as practicable of the required information be contained in a single document to be known as the 'Radiation Protection File'. An RPA and MPE will be able to give advice on the detailed content of this File in the light of the particular requirements of the practice. This appendix provides guidance on the general content required.
- A4.2** The Radiation Protection File should be reviewed periodically to ensure that it remains relevant and effective. A log should be maintained to record each occasion on which the File was reviewed or modified (see paragraph 5.25).
- A4.3** The *Legal Person* must ensure that the Local Rules, and the remainder of the contents of the Radiation Protection File, are brought to the attention of those affected by their contents.

Content deriving from IRR99

Local Rules

- A4.4** The Local Rules must contain at least the following information:
- (a) name(s) of the appointed radiation protection supervisor(s);
 - (b) the identification and description of each controlled area and a summary of the arrangements for restricting access;
 - (c) an appropriate summary of the working instructions;
 - (d) identification or summary of any contingency arrangements indicating the reasonably foreseeable accidents to which they relate;
 - (e) the dose investigation level.
- Further advice about (c), (d) and (e) is given below.
- A4.5** The *Legal Person* is also recommended to include in the Local Rules:
- (a) the identity of the person with legal responsibility for the use of the x-ray equipment (see paragraph 2.2);
 - (b) contact details of the RPA;
 - (c) arrangements for personal dosimetry (see paragraph 3.7 and 3.8);
 - (d) arrangements for pregnant staff (see paragraph 2.19);
 - (e) a reminder to employees of their legal responsibilities under IRR99 (see paragraph 2.28);

- (f) **a brief mention** of the fact that the following exist and that full details can be found in the Radiation Protection File:
- arrangements for the maintenance and testing of equipment (see paragraphs 3.16 to 3.20);
 - details of the significant findings of the risk assessment (see Appendix 2);
 - procedures for ensuring staff have received adequate information, instruction and training (see paragraphs 2.20 to 2.23);
 - the programme for review to ensure that the Local Rules remain up to date and effective (see paragraphs 5.23 and 5.25), thereby effectively ensuring that doses to staff and other persons are kept as low as reasonably practicable (see paragraph 2.18);
 - the arrangements for investigating and reporting incidents, such as excessive exposure of patients or staff, including the notifying of appropriate authorities (see paragraphs 2.51 to 2.56).

Working instructions

A4.6 The Local Rules should contain the key working instructions and responsibilities intended to restrict exposure to radiation. In particular, for routine operation, they should require staff to stand well outside of the controlled area (ie well out of the direction of the primary beam, and preferably, at least 2 m from the x-ray tube head and patient), and behind any protective panels provided. Special instructions should relate to those occasions when a person needs to enter the controlled area. In addition, if the normal structural material of a wall does not afford sufficient shielding (eg a light-weight partition wall without additional shielding), the Local Rules should prohibit the direction of the primary beam towards that wall.

A4.7 If it is necessary for a member of staff or other person to enter the controlled area in order to support a handicapped patient or child, written arrangements for the restriction of their exposure must be drafted, in consultation with an RPA, and should be included in the Local Rules (see paragraph 3.22).

Contingency arrangements

A4.8 In the risk assessment, the *Legal Person* must consider possible accident situations, their likelihood and potential severity. This will allow the *Legal Person* to determine what contingency plans are necessary to address reasonably foreseeable accidents.

A4.9 Examples of situations that are reasonably foreseeable and for which contingency plans should be drawn up are:

- (a) failure of the x-ray control circuitry, such that an exposure does not terminate after a preset condition;
- (b) failure of the rotational movement of panoramic equipment;
- (c) damage to the lead shielding around the tube head as a result of a surgery fire or mechanical damage.

A4.10 During each exposure, the *operator* needs to be able to see the exposure warning light and hear the audible warning. If the warning(s) indicate that an exposure has failed to terminate after a preset condition (eg exposure time), the *operator* should immediately release the irradiation switch. If the rotational movement of panoramic equipment fails to start or stops before the full arc is covered, the *operator* should immediately release the irradiation switch to avoid high, localised exposure of the patient.

A4.11 In the event of any fault or damage to the x-ray tube head, the equipment should be disconnected from the mains supply and not used again until it has been checked and, if necessary, repaired by a service engineer.

Dose investigation level

A4.12 In the risk assessment, the *Legal Person* should have set a dose investigation level. Although the *Legal Person* is free to choose (in consultation with an RPA) any level up to and including 15 mSv per year, a dose investigation level of no higher than 1 mSv per year is recommended as generally appropriate for dental radiography. The chosen dose level must be specified in the Local Rules.

A4.13 If personal monitoring records, or other information, indicate that a member of staff may have exceeded the dose investigation level, the *Legal Person* must undertake a formal review of working conditions to make sure that exposure is being restricted as far as reasonable practicable. This review should normally be carried out in conjunction with an RPA and a copy of the investigation report kept for at least two years.

Content deriving from IR(ME)R2000

Legal Person's procedures

A4.14 IR(ME)R2000 requires that the *Legal Person* establish written procedures to include:

- (a) correct identification of the patient prior to radiography;
- (b) identification of individuals entitled to act as *referrer* or *IRMER practitioner* or *operator*;
- (c) medico-legal exposures (see paragraphs 2.36 and 2.37);
- (d) making enquires of female patients of child-bearing age to establish whether the individual is or may be pregnant (see paragraphs 2.38 to 2.40);
- (e) ensuring that quality assurance programmes are followed (see paragraph 5.28);
- (f) the assessment of patient dose (see paragraph 3.18);
- (g) the use of diagnostic reference levels (see paragraphs 2.47 to 2.49);
- (h) the carrying out and recording of a clinical evaluation of the outcome of each exposure (see paragraphs 2.45 and 2.46);
- (i) ensuring the probability and magnitude of accidental or unintended doses to patients are reduced so far as reasonably practicable;
- (j) provision for the carrying out of clinical audits⁽²⁷⁾ as appropriate (see paragraph 5.29).

Further advice about (a), (b) and (i) is given below.

A4.15 In addition, the *Legal Person* is required to establish:

- (a) guidelines for referral criteria for radiographic examinations (see paragraph 2.31);
- (b) written protocols (guideline exposure settings) for every type of standard projection for each item of equipment (see paragraph 2.42);
- (c) quality assurance programmes (see Chapter 5 for details of a full QA programme covering both equipment and procedures – strictly this reference, within IR(ME)R2000, refers only to the procedural aspects);
- (d) diagnostic reference levels (see paragraphs 2.47 to 2.49);
- (e) the method for authorising each exposure, to ensure that there is a record that justification has taken place (see paragraphs 2.32 to 2.35).

Patient identification

A4.16 The *Legal Person* is required to establish procedures for the correct identification of patients prior to radiography. Where the *referrer* and the *operator* carrying out the radiography is the same person, formal patient identification prior to radiography should be unnecessary.

A4.17 If the *operator* carrying out the radiography is not the same person as the *referrer*, the *operator* must follow the identification procedure established by the *Legal Person*. The procedure should be positive, active and be capable of uniquely identifying a patient, eg “What is your name?, What is your address?, What is your date of birth?”. Before carrying out an exposure, the *operator* needs to have personally identified each patient.

Staff appointments

A4.18 The *Legal Person* must clearly define who is allowed to act as a *referrer*, an *IRMER practitioner*, and an *operator*. As *operators* have a number of functions, the range of functions that an individual *operator* is allowed to perform should also be clearly defined. The *Legal Person* must also ensure that all staff are adequately trained before undertaking their duties (see Appendix 3 for details).

A4.19 Where agency staff or locums are employed, the *Legal Person* should ensure that contractual arrangements are in place stipulating the range of functions that any *IRMER practitioner* or *operator* will be expected to undertake and that they must have been adequately trained.

Accidental or unintended dose

A4.20 The *Legal Person* must include, within the standard operating procedures, a requirement that all practical aspects of radiography should be conducted with due regard to minimising accidental or unintended doses to patients.

Appendix 5 Guidance on the testing of dental x-ray equipment

A5.1 Paragraph 3.18 includes the following:

'All dental x-ray equipment must be subject to the following tests:

- (a) a 'critical examination' by the installer, immediately following installation;*
- (b) an adequate test before the equipment is put into clinical use (the 'acceptance test');*
- (c) further adequate tests at appropriate intervals ('routine tests') and after any major maintenance procedure;*
- (d) at suitable intervals, measurements to assess representative patient doses.'*

An RPA should be consulted with respect to all aspects of each of the above categories of test.

A5.2 Attention is drawn to an IPEM report concerning 'Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems'⁽³¹⁾.

Critical examination

A5.3 It is the responsibility of the installer to undertake the 'critical examination' but the *Legal Person* is advised to ensure that an adequate critical examination report is obtained. The installer must consult with an RPA, appointed by himself or by the *Legal Person*, with regard to the nature and extent of any critical examination and the results of that examination.

A5.4 The essential content of a 'critical examination' and associated report involves:

- (a) a clear and unambiguous description of the equipment and the location at which it is installed;
- (b) an evaluation of the acceptability of the location in relation to:
 - the recommendations contained in paragraphs 3.9 to 3.14;
 - the *operator's* position;
 - the room warning signals, if applicable;
- (c) an evaluation of the acceptability of the equipment's warning signals;
- (d) an evaluation of the acceptability of the exposure control;
- (e) confirmation that sufficient radiation protection and safety features are in place and operating correctly (eg beam dimensions and alignment, beam filtration and timer operation);

- (f) an evaluation of the acceptable functioning of any other safety systems that are fitted (eg safety cut out switches on panoramic equipment). This should include those mechanical and electrical systems whose malfunction could impact on radiation safety (eg rotational movement and braking on panoramic equipment, effective counterbalance mechanisms on arms supporting intra-oral x-ray tubes).

A5.5 The critical examination report should incorporate an overall conclusion as to whether or not:

- (a) the equipment's safety features are operating correctly;
- (b) the installation is providing sufficient protection for persons from exposure to x-rays;
- (c) a statement as to whether the user has been provided with 'adequate information about proper use, testing and maintenance of the equipment'.

Acceptance test

A5.6 It is the responsibility of the *Legal Person* to ensure that the 'acceptance test' and subsequent 'routine tests' (see paragraph A5.8) are carried out. These tests form a part of the *Legal Person's* QA programme, about which an RPA should be consulted.

A5.7 Paragraphs 542 and 543 of the ACoP that supports IRR99⁽¹⁾ emphasises the need for the acceptance test to provide baseline values against which the results of subsequent routine tests can be compared. The essential content of an 'Acceptance Test' then becomes:

- (a) all the components given at paragraph A5.4;
- (b) measurements to determine whether the equipment is operating correctly within agreed performance parameters (eg operating potential, x-ray output, timer accuracy);
- (c) an assessment of the typical patient dose for comparison with the Diagnostic Reference Level (see paragraphs 2.47 to 2.49).

Routine test

A5.8 A 'routine test' will be essentially similar in content to an 'acceptance test', but a different emphasis will be appropriate, such as:

- (a) it will only be necessary to confirm that there have been no significant changes to the description of the equipment and location, and the ongoing acceptability of the location;
- (b) attention needs to be paid not only to the actual results of the technical tests, but also how they compare to the results of previous tests. It will be necessary to identify and investigate trends that suggest possible deterioration.

Results of tests

- A5.9** The *Legal Person* should ensure that persons making any relevant tests provide a permanent record of the results and conclusions of all tests, and these records should be retained as part of the QA programme. Recommendations should be made to rectify any identified deficiencies.
- A5.10** Recommendations that arise out of tests need to be followed up and the *Legal Person* should ensure that resulting actions and their outcome are recorded within the QA programme. In this respect it is particularly important to take effective action to reduce patient doses that consistently exceed DRLs.

Appendix 6 Essential legal requirements

A6.1 This appendix summarises the essential legal requirements contained within IRR99 and IR(ME)R2000. It also provides a simple indexing facility to enable the reader to quickly locate the primary source(s) of information, within these GNs, for each requirement. Legal Persons are reminded that these GNs contain a lot more than is summarised in this appendix and are referred to the comments in paragraph 1.17 concerning clinical governance.

A6.2 Essential legal requirements arising out of IRR99

Regulation	Requirement	Primary location(s) within these GNs
5	Authorisation. Use of dental x-ray equipment for research purposes should be in accordance with a generic authorisation granted by HSE.	Paragraph 2.11
6	Notification. HSE must be notified of the routine use of dental x-ray equipment and of any material changes to a notification.	Paragraphs 2.9 and 2.10 and Appendix 1
7	Prior risk assessment. This must be undertaken before work commences and be subject to regular review.	Paragraphs 2.13 to 2.16, and Appendix 2
8	Restriction of exposure. An over-riding requirement to restrict radiation doses to staff and other persons to as low as reasonably practicable.	Paragraph 2.18
10	Maintenance and examination of engineering controls, etc. Applies particularly to safety and warning features of dental x-ray equipment.	Paragraphs 3.16 and 5.16
12	Contingency plans. These should arise out of the risk assessment and be provided within the Local Rules.	Appendix 4 (A4.4 and A4.8 to A4.11)
13	Radiation Protection Adviser. An RPA must be consulted and appointed in writing when the <i>Legal Person</i> requires advice in relation to IRR99.	Paragraph 2.7
14	Information, instruction and training. Must be provided, as appropriate, for all persons associated with the dental radiology.	Paragraphs 2.20, 2.21 and 2.23
16 and 18	Designated areas. A controlled area will normally be designated as an aid to the effective control of exposures.	Paragraphs 3.2 to 3.6
17	Local Rules and Radiation Protection Supervisor (RPS). Strictly only a legal requirement if a controlled area is designated. Recommended as good practice in all situations.	Paragraphs 2.3, 2.24 and 2.27 and Appendix 4 (A4.4 to A4.13)

Regulation	Requirement	Primary location(s) within these GNs
20	Classified persons. Unlikely to be required, but may depend on workload.	Paragraphs 3.7 and 3.8
31	Duties of manufacturers, etc. New or significantly modified equipment must be 'critically examined' by the installer.	Paragraphs 3.16 and 3.17, and Appendix 5 (A5.3 to A5.5)
32	Equipment used for medical exposure. Requires a QA programme which shall include adequate testing of dental x-ray equipment prior to first clinical use and routinely thereafter. Lays down procedures to follow if a patient is suspected of having received an excessive exposure as a result of an equipment defect or malfunction.	Paragraphs 2.51 to 2.57, 3.18 and Appendix 5 (A5.6 to A5.10) Chapter 5 for the full QA programme.
34	Duties of employees. Places duties on all employees.	Paragraph 2.28

A6.3 Essential legal requirements arising out of IR(ME)R2000

Regulation	Requirement	Primary location(s) within these GNs
4	Duties of employers. The <i>Legal Person</i> is required to provide a framework of 'written procedures' for medical exposures. These include procedures to follow if a patient is suspected of having received an excessive exposure as a result of any occurrence other than an equipment defect or malfunction.	Paragraphs 2.25 to 2.26, 2.51 to 2.56, and Appendix 4 (A4.14 to A4.20).
5	Duties of the practitioner, operator and referrer. Lays down the responsibilities placed on these appointed persons.	Paragraphs 2.4 to 2.6
6	Justification of individual medical exposures. Lays down conditions to be met before a medical exposure can be carried out.	Paragraphs 2.32 to 2.35
7	Optimisation. In relation to dental radiology, doses to patients must be kept as low as reasonably practicable consistent with the intended purpose. This includes the need to apply QA procedures to the optimisation of patient dose.	Paragraphs 2.41 to 2.50, and 2.57 Chapter 5 for the full QA programme.
8	Clinical audit. Provisions must be made for clinical audit, as appropriate.	Paragraph 5.29 and Appendix 4 (A4.14)
9	Expert advice. Lays down the need for, and involvement of, a Medical Physics Expert.	Paragraph 2.8
10	Equipment. The keeping and maintenance of an inventory of dental x-ray equipment.	Paragraph 5.17
11	Training. Lays down training requirements for <i>IRMER practitioners</i> and <i>operators</i> .	Paragraphs 2.22, 2.23 and 5.26 and Appendix 3

Appendix 7 Useful addresses and list of abbreviations employed in these Guidance Notes

A7.1 Useful addresses – organisations

Organisation and contact details	Role
<p>Health and Safety Executive (HSE) Rose Court 2 Southwark Bridge Road London SE1 9HS Tel: 020 7717 6000 InfoLine: 0541 545500 http://www.hse.gov.uk/hthdir/noframes/iradiat.htm</p>	<p>Ionising Radiations Regulations 1999 and associated Code of Practice and Guidance</p>
<p>Health and Safety Executive, Northern Ireland 83 Ladas Drive Belfast BT6 9FR Tel: 02890 243249 http://www.hseni.gov.uk/</p>	<p>Ionising Radiations Regulations 1999 and associated Code of Practice and Guidance for Northern Ireland</p>
IRMER Inspectorate:	
<p>England: Inspectorate of the Secretary of State for Health for IR(ME)R2000, Room 323, Wellington House, 133–155 Waterloo Road London SE1 8UG Tel: 020 7972 4801/4802/4185/4986 Fax: 020 7972 4800</p>	<p>Ionising Radiations (Medical Exposure) Regulations 2000 and Guidance</p>
<p>Scotland: Scottish Executive Health Department, St Andrews House Regent Road Edinburgh EH1 3DG Tel: 0131 244 2495</p>	
<p>Wales: National Assembly for Wales Cathays Park Cardiff CF10 3NQ</p>	
<p>Northern Ireland: Room C3.8, Castle Buildings Upper Newtownards Road Belfast BT4 3PP Tel: 02890 520710</p>	

Organisation and contact details	Role
<p>Medical Devices Agency Hannibal House Elephant and Castle London SE1 6TQ Tel: 020 7972 8000 Email: mail@medical-devices.gov.uk http://www.medical-devices.gov.uk</p>	<p>Medical Devices Regulations 1994. Responsible for:</p> <ul style="list-style-type: none"> ensuring that medical devices and equipment in the UK comply with relevant Euratom Directives and meet acceptable standards of safety, quality and effectiveness for evaluation of medical devices for the investigation of incidents and the dissemination of safety information
<p>MDA Adverse Incident Centre Medical Devices Agency Hannibal House Elephant and Castle London SE1 6TQ Tel: 020 7972 8080 Fax: 020 7972 8109</p>	<p>For receiving reports of adverse incidents. Full information for reporting such incidents can be found at: http://www.medical-devices.gov.uk/sn2000(01).htm</p>
<p>National Radiological Protection Board Chilton Didcot Oxfordshire OX11 0RQ Tel: 01235 831600 Fax: 01235 833891 email: Information@nrpb.org.uk</p>	<p>Radiation protection advice</p>
<p>Northern Ireland Regional Medical Physics Agency Forster Green Hospital 110 Sainfield Road Belfast BT8 4HD Tel: 02890 793681</p>	<p>General advice and services in Northern Ireland</p>
<p>Scottish Health Service Common Services Agency Scientific and Technical Branch Trinity Park House South Trinity Road Edinburgh EH5 3SH Tel: 0131 552 6255</p>	<p>Radiological equipment in Scotland</p>

A7.2 Useful addresses – professional bodies

BDA	British Dental Association 64 Wimpole Street London W1G 8YS Tel: 020 7935 0875
BDTA	British Dental Trade Association Mineral Lane, Chesham Buckinghamshire HP5 1NL Tel: 01494 782873 Fax: 01494 786659 E-mail: admin1@bdta.org.uk http://www.bdta.org.uk
BIR	British Institute of Radiology 36 Portland Place London W18 1AT Tel: 020 7307 1400 Fax: 020 7307 1414
CoR	The Society and College of Radiographers 207 Providence Square Mill Street London SE1 2EW Tel: 020 7740 7200 E-mail: info@sor.org
FGDP(UK)-RCS	Faculty of General Dental Practitioners (UK) of the Royal College of Surgeons of England 35–43 Lincoln Inns Fields London WC2A 3PN Tel: 020 7312 6671 E-mail: fgdp@rcseng.ac.uk
IPEM	Institute of Physics and Engineering in Medicine Fairmount House 230 Tadcaster Road York YO24 1ES Tel: 01904 610821 http://www.ipem.org.uk
RCN	Royal College of Nursing 20 Cavendish Square London W1M 0AB Tel: 020 7647 3861 Fax: 020 7647 3441 http://www.rcn.org.uk
RCR	Royal College of Radiologists 38 Portland Place London W1N 4JQ Tel: 020 7636 4432 Fax: 020 7323 3100 E-mail: enquiries@rcr.ac.uk

A7.3 Abbreviations used in this document

The most frequently used abbreviation is quite simply ‘GNs’ to refer to these Guidance Notes. Many others had to be used and, for convenience, all are listed below in alphabetical order.

(a) Technical abbreviations

Abbreviation	Full meaning
ACoP	Approved Code of Practice, that supports the Ionising Radiations Regulations 1999
CE	Conformite Europeene
CPD	Continuing Professional Development
DRL	Diagnostic Reference Level
FSD	Focus-to-skin distance
GNs	Guidance Notes (for Dental Practitioners on the Safe Use of X-ray Equipment)
IR(ME)R2000	Ionising Radiation (Medical Exposure) Regulations 2000
IRR85	Ionising Radiations Regulations 1985
IRR99	Ionising Radiations Regulations 1999
MHSWR99	Management of Health and Safety at Work Regulations 1999
MPE	Medical Physics Expert
PCD	Professional Complementary to Dentistry
QA	Quality assurance
RPA	Radiation Protection Adviser
RPS	Radiation Protection Supervisor
WP	Working Party responsible for these Guidance Notes

(b) Organisational names

BDA	British Dental Association
BDTA	British Dental Trade Association
BIR	British Institute of Radiology
CoR	The College of Radiographers
DNSTAB	Dental Nurses Standards and Training Advisory Board
DH	Department of Health
FGDP-RCS	Faculty of General Dental Practitioners (UK) of the Royal College of Surgeons of England
GDP	General Dental Practitioner
HSE	Health and Safety Executive
IPEM	Institute of Physics and Engineering in Medicine
MDA	Medical Devices Agency
NRPB	National Radiological Protection Board
RCN	Royal College of Nursing
RCR	Royal College of Radiologists
UK	United Kingdom

References

1. Tanner R J, Wall B F, Shrimpton P C, Hart D and Bungay D R. Frequency of Medical and Dental X-ray Examinations in the UK 1997/98. Chilton, NRPB-R320 (2000)
2. ICRP. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Annals of the ICRP, 21, Nos 1–3 (1991)
3. EC. Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of health of workers and the general public against the dangers arising from ionising radiation. Official Journal of the European Communities 39, L159, 1–114 (1996)
4. EC. Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Official Journal of the European Communities 40, L180 (1997)
5. The Ionising Radiations Regulations 1999. SI 1999 No 3232. London, the Stationery Office (1999). ISBN 0 11 085614 7
6. The Ionising Radiation (Medical Exposure) Regulations 2000. SI 2000 No 1059. London, the Stationery Office (2000). ISBN 0 11 099131 1
7. IPEM. Medical and Dental Guidance Notes. A good practice guide to implement ionising radiation protection legislation in the clinical environment. York, IPEM (in draft)
8. Health and Safety at Work etc Act 1974. London, HMSO (1974). ISBN 0 10 543774 3
9. Management of Health and Safety at Work Regulations 1999. SI (1999) No 3242. London, the Stationery Office (1999). ISBN 0 11 085625 2
10. Safe Use of Work Equipment, ACoP and guidance on the Provision and Use of Work Equipment Regulations 1998. Sudbury, HSE Books L22 (1998). ISBN 0 7176 1626 6
11. Work with ionising radiation. Ionising Radiations Regulations 1999. Approved Code of Practice and Guidance. Sudbury, HSE Books L121 (2000). ISBN 0 7176 1746 7
12. NRPB. Guidelines on Patient Dose to Promote the Optimisation of Protection for Diagnostic Medical Exposures. Documents of the NRPB, 10, No 1 (1999)
13. Rushton VE, Horner K, Worthington HV. The quality of panoramic radiographs in a sample of general dental practices. British Dental Journal 186:630–633 (1999)
14. Rushton VE and Horner K. A comparative study of radiographic quality with five periapical techniques in general dental practice . Dentomaxillofac Radiol 23:37–45 (1994)
15. HSE statement on Radiation Protection Advisers. Available from the HSE website, as at February 2001.
16. FGDP (UK). Selection Criteria for Dental Radiography (1998). London, Royal College of Surgeons of England. ISBN 0 952 053799
17. British Orthodontic Society. Guidelines for the use of Radiographs in Clinical Orthodontics. (In press, 2001)

18. Napier I D. Reference doses for dental radiography. *British Dental Journal* 186:392–396 (1999)
19. HSE. Fitness of equipment used for medical exposure to ionising radiation. Sudbury, HSE, Guidance Note PM77 (1992)
20. Medical Devices Regulations 1994. SI 1994 No 3017. London, HMSO (1994). ISBN 0 11 043255 X
21. Safety signs and signals. The Health and Safety (Safety Signs and Signals) Regulations 1996. Guidance on Regulations. Sudbury, HSE Books L64 (1996). ISBN 0 7176 0870 0
22. EC. Medical Devices Directive 93/42/EEC. Opinion on the proposal for a Council directive concerning medical devices. *Official Journal of the European Communities* 1992, 5, No C79 1–3 (1992)
23. BS EN 606 01–1–3:1995. Medical electrical equipment. Part 1. General requirements for safety. Section 1.3 Collateral standard: General requirements for radiation protection in diagnostic x-ray equipment. London, BSI (1995). ISBN 0 580 23595 5
24. BS 60601–2–28:1993. Medical electrical equipment. Part 2. Particular requirements for safety of x-ray source assemblies and x-ray tube assemblies for medical diagnosis. London, BSI (1993). ISBN 0 580 22235 7
25. Report of a joint working party of the British Society for the Study of Orthodontics and the British Society of Dental and Maxillofacial Radiology. Reduction of the dose to patients during lateral cephalometric radiography. *British Dental Journal* 158:415 (1985)
26. NRPB. Guidelines on Radiology Standards for Primary Dental Care. *Documents of the NRPB*, 5, No 3 (1994)
27. DH. Peer Review and Clinical Audit in General Dental Practice (known as the Green Book). National Centre for Continuing Professional Education of Dentists on behalf of DH (1997) (revised 2000)
28. The first five years. The undergraduate dental curriculum. London, General Dental Council (1997)
29. DSASTAB (now DNSTAB) and CoR. Dental Radiography Course for Dental Surgery Assistants. London, CoR 1994 (Currently under review)
30. The Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988. SI 1988 No 778. London, HMSO (1988). ISBN 0 11 086778 5
31. IPEM. Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems. York, IPEM Report No 77 (1998)

This document can be found on the internet
at www.nrpb.org.uk

ISBN 0 85951 463 3

Copyright on this document is held by NRPB,
to whom all technical enquiries should be
addressed. The document can be reproduced
without formal permission or charge for
personal or in-house use provided that
acknowledgement is made. The contents must
not be extracted, altered, quoted or used for any
commercial purpose without NRPB's prior
written consent.

Further copies of these Guidance Notes are
available from:

National Radiological Protection Board
Information Services
Chilton, Didcot
Oxon OX11 0RQ
[information@nrpb.org.uk]

© National Radiological Protection Board – 2001

Printed by the Department of Health