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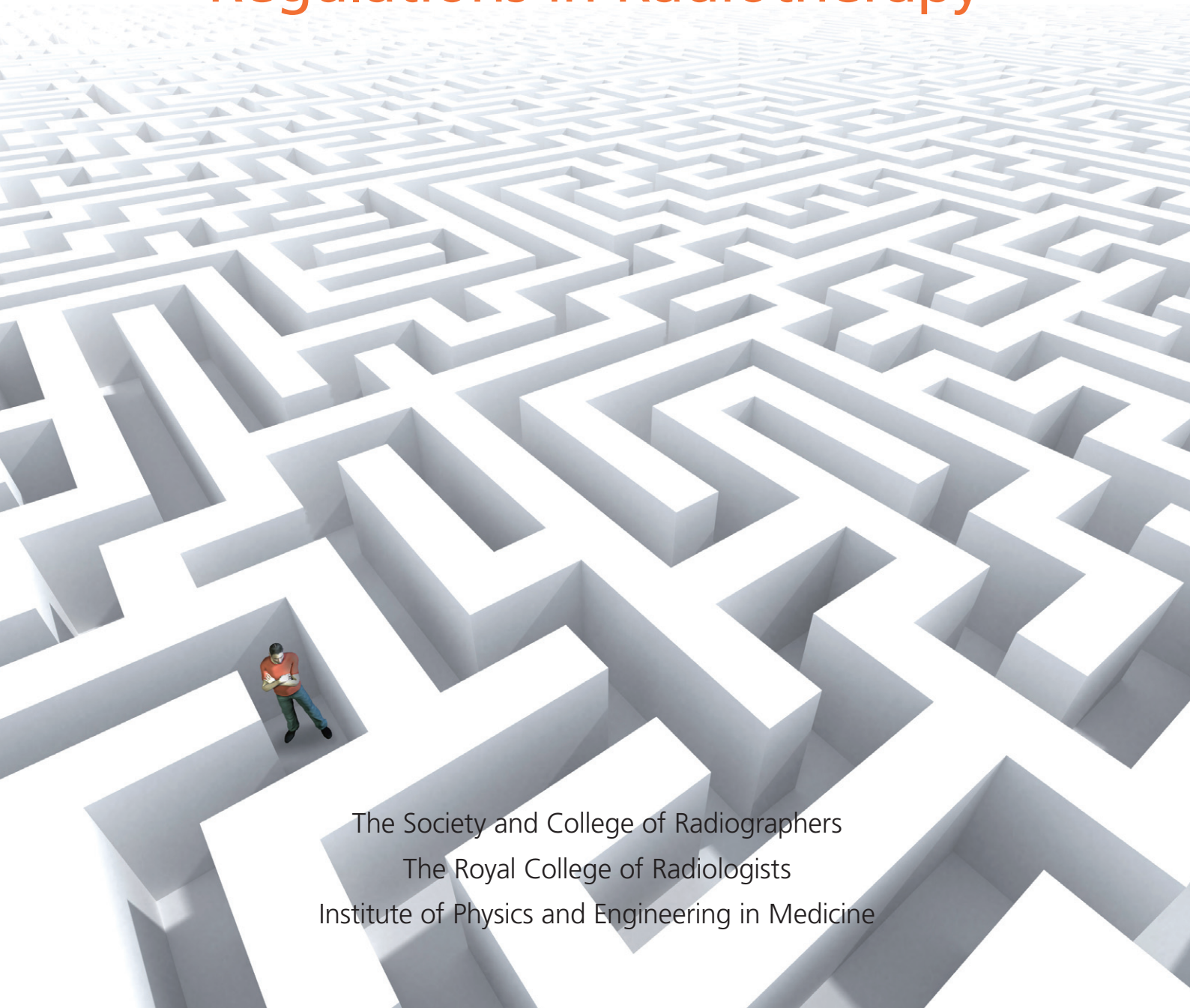
A Guide to Understanding the Implications of the Ionising Radiation (Medical Exposure) Regulations in Radiotherapy



The Society and College of Radiographers
The Royal College of Radiologists
Institute of Physics and Engineering in Medicine

Do you know that?

- IR(ME)R is aimed at protecting patients (see Section 1.2)
- IR(ME)R is legislation made as criminal law rather than civil law (see Section 1.2 and 5.11)
- Duty holders under IR(ME)R

  A ***referrer***, who requests that the patient is treated, is required to provide sufficient clinical information to allow justification of the treatment (see Section 2.6)

  A ***practitioner*** is responsible for justifying any radiation exposure (see Section 2.8). (Justification is the process of weighing up the potential benefits of the exposure against the potential detriment to the individual.)

  An ***operator*** is personally responsible for their own contribution to the patient's treatment (see Section 2.12)
- Practitioners and operators are required to follow defined written protocols (see Section 4.1)
- Human error that leads to a radiation exposure 'much greater than intended' must be reported to the responsible authority (see Section 5.3)
- In the event of an error resulting from a breach of regulations, individuals or employers may be prosecuted (see Sections 5.9 and 5.11)
- The employer has a statutory duty to make sure written procedures, written protocols and quality assurance programmes are in place (see Sections 1.3 and 4.1)
- The employer is responsible for ensuring that practitioners and operators are adequately trained and keeping records of this training (see Section 2.3)
- When an *operator* task is being undertaken 'under supervision', the supervisor is fully responsible as *operator* for that task (see Section 2.19)
- All exposures must be justified and authorised before they are made, and the signed prescription is the evidence of authorisation that treatment can proceed (see Section 3.2)
- Your signature means that you are taking responsibility for that specific part of the radiotherapy process. It would be inappropriate for you to sign for something outside your control, for which you have not been trained and do not have the tools to complete. Written procedures should explicitly state which duty holder is responsible for each element of a process (see Sections 3.2–3.4)
- When several staff are involved in a particular task, the employer must define in written procedures whether they all have equal legal responsibility or whether one person is acting as the responsible operator for the purpose (see Sections 3.5 and 3.12)
- When using the word 'check' in a written procedure, it must define exactly what is meant and what an individual is required to do and what responsibility they have (see Section 3.13)
- When checking something is correct, you should always seek to find ways to carry out a process in a different way to maximise the chance of identifying an error (see Sections 3.13 and 3.15)
- If an operator initiates treatment without evidence of a check being completed, they are then held responsible if it has not been done (see Section 3.13)
- The arrangements for justifying and authorising radiotherapy exposures for out-of-hours emergencies should be as robust as those in place during the normal working day (see Section 3.18)

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Foreword

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 is legislation intended to protect the patient from the hazards associated with ionising radiation. Major errors within radiotherapy are reported under IR(ME)R and investigations are conducted under criminal law and under the threat of caution. This may be seen as at odds with the development of a no blame culture, but serves to emphasise appropriate responsibility.

IR(ME)R compliance has not yet been tested in the courts, and there is confusion among radiotherapy professionals about the implications of IR(ME)R for their practice.

The objective of the Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) Working Party was to bring together representatives from the professional bodies representing clinical oncology, therapeutic radiography and radiotherapy physics to produce a guide to help employers and clinical colleagues understand and implement IR(ME)R legislation as it pertains to radiotherapy. The College is grateful to the Health Protection Agency (HPA) for expert advice.

A series of frequently asked questions has been produced to help the reader navigate their way through IR(ME)R. This guidance is not intended to be definitive and there is not a single correct answer; the advice given is wide-ranging and does not undermine an *employer's* legal responsibilities for implementing compliant local procedures.

This document should be read in conjunction with IR(ME)R and published guidance.

I would like to thank Dr David Bloomfield (chair), Dr Sian Davies, Steve Ebdon-Jackson, Michael Graveling, Philip Mayles, Maria Murray and Carol Nix for their work in producing this document. I would also like to thank the referees for their helpful comments.

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1 Introduction

1.1 Who is this working party document for?

This guide will be of benefit to chief executives, medical directors, human resources departments and all professionals involved in the delivery of radiotherapy.

1.2 The purpose of this working party document

The objective of the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)[1] Working Party was to bring together representatives from the professional bodies representing clinical oncology, therapeutic radiography and radiotherapy physics to produce a guide to help employers and clinical colleagues in UK cancer centres understand and implement IR(ME)R legislation as it pertains to radiotherapy. The Health Protection Agency was also represented on the working party.

IR(ME)R[1] is legislation aimed at the protection of the patient against the hazards associated with ionising radiation. It is made as criminal law rather than civil law. The main difference being that if there is a breach of civil law then the law seeks to establish fault and award compensation; in criminal law, an illegal act is punished, compensation is a secondary issue.

To date, IR(ME)R compliance has not been tested in the courts, and there is confusion and understandable anxiety among radiotherapy professionals around the implications of IR(ME)R to their practice.

A fundamental principle is that IR(ME)R is flexible and allows a wide variety of practices to be undertaken as long as they are clearly justified. It is imperative that roles and responsibilities are clearly set out in procedures and that everyone understands their individual role.

Responsibility for compliance with IR(ME)R rests with the *employer* and all *entitled* duty holders as defined in the regulations. It is neither possible nor advisable to deliver a template for national use. There is a wide range of good practice which can take into account local needs. We aim to describe commonly encountered clinical situations and provide examples of good practice.

As definitive interpretation of the law can only be established in the courts, the guidance given here should be regarded as an expression of professional opinion rather than as a definitive statement of the legal position.

This document aims to address a series of frequently asked questions (FAQs) which have come up in formal inspections or have been brought to the attention of the Working Party by its members from their own departments and professions. This document should be read in conjunction with IR(ME)R and published guidance.[1–3]

1.2.1 Definitions used throughout this document

'Clinical oncologist' means a specialist doctor trained in the non-surgical management of cancer using radiotherapy and accredited through the Fellowship examination of The Royal College of Radiologists (FRCR) or equivalent approved training.

'Physicist' means an individual who has carried out training as a radiotherapy physicist. Where a physicist registered with the Health Professions Council is intended in this document, 'clinical scientist' is used.

'Radiographer' means a therapeutic radiographer registered with the Health Professions Council (HPC).

Quotations from the Regulations are shown in italics and italics are also used to indicate that words such as *'practitioner'*, *'operator'* and *'entitled'* have the specific IR(ME)R meanings.

The examples quoted are taken from documents provided to the Working Party by several trusts and are not intended to be prescriptive.

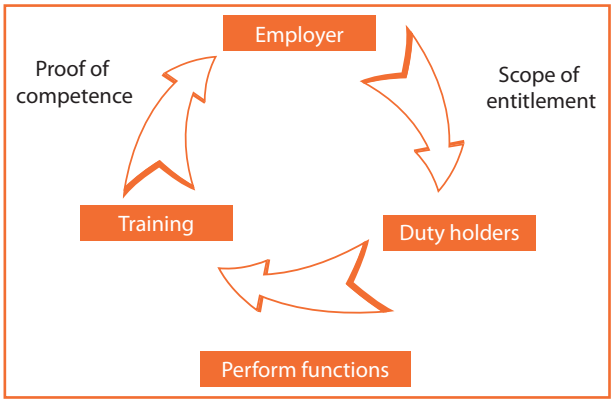
1.3 The Ionising Radiation (Medical Exposure) Regulations 2000

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)[1] derive from the European Council Medical Exposures Directive.[4] They are designed to ensure patient safety and were made under Section 2(2) of the European Communities Act 1972[5] but are enforced as if made under Section 15 of the Health and Safety at Work etc. Act 1974.[6] Guidance on the application of IR(ME)R is provided by the Medical and Dental Guidance Notes[2] (which also covers the medical application of the Ionising Radiations Regulations [IRR]).[7] This was produced by a working group of the Institute of Physics and Engineering in Medicine (IPEM) in association with the National Radiological Protection Board (NRPB – now the Health Protection Agency Radiation Protection Division; HPA-RPD), the Health and Safety Executive, the Health Departments and the Environment

Agencies and in co-operation with The Royal College of Radiologists and the Society and College of Radiographers. Non-statutory guidance was issued by the Department of Health (DH).[3] Both of these guidance documents would need to be supported in court by an expert witness, but provide a basis for action.

The essential elements of IR(ME)R are presented in Figure 1.

Figure 1. Essential elements of IR(ME)R



The concept of 'entitlement' is not well understood in medicine but is required within IR(ME)R. In entitling professionals to act as duty holders, the *employer* must also specify the scope of this entitlement. This is most obvious for *operators*, who undertake a range of functions, but applies to all duty holders and is consistent with clinical governance and good professional practice. The scope of entitlement of any individual is supported by their training records, which demonstrate that the individual is competent to undertake specific functions.

This approach allows for development of duty holders and extension of their scopes of entitlement, as long as this can be supported by evidence of training.

1.3.1 Definition of roles

IR(ME)R ***(Regulation 2)*** defines four duty holders, including the *employer* and three distinct types of duty holder who provide a professional contribution to radiation therapy (and diagnosis). The duties of the *employer* are defined in ***Regulation 4*** and the duties associated with the other professional roles are defined in ***Regulations 5*** and ***9***. These are:

- The *referrer* who requests that the patient is treated and is required to provide sufficient clinical information to allow the justification of the treatment to be determined. In the EU legislation, the term used is the 'prescriber', but this is not the interpretation applied in the UK regulations.
- The *practitioner* who is responsible for the medical exposure and for justifying any radiation exposure. The use of the word 'practitioner' is unfortunate because it has become associated with role extension in health service professional groups. The term 'justifier' may better describe the role. As the *practitioner* may allocate ***(Regulation 5(3))*** practical aspects of the medical exposure to others, there is an implication that the *practitioner* has the clinical oversight of the treatment.
- The *operator* who carries out any *practical aspect* of the treatment process (including, for example, machine calibration or treatment planning). This role is not expressly recognised in the EU directive. IR(ME)R states that all *operators* are personally responsible for their own contribution to the patient's treatment.

In addition, the Regulations identify the *medical physics expert* (MPE) as a specific *operator.* The MPE must be *closely involved* in all radiotherapy treatment.

The Regulations do not define who may fulfil these roles, except that the *referrer* and *practitioner* are required to be *registered healthcare professionals*, but require that each *employer* produces a list of named individuals *entitled* to act as *practitioner or operator* together with a record of their training ***(Regulation 11)***. The *employer* must establish procedures to define who may act as *referrer*, *practitioner* or *operator* ***(Schedule 1b)***.

1.3.2 Justification

Regulation 6 addresses *justification* of exposures. This requires that the benefit and detriment of the exposure are considered by the *practitioner*, taking into account the intention of the exposure and the characteristics of the individual patient. In radiotherapy, a whole course of treatment fractions intended to provide a therapeutic effect is considered and *justified* as one total exposure. Any necessary planning and verification exposures, if specified as part of a protocol, can be *justified* at the same time, or alternatively can be *justified* separately. Any such exposures performed that are not covered by the protocol must be justified separately.

Optimisation

Regulation 7, which deals with *optimisation* of exposures, includes the requirement that exposures of target volumes are individually planned to ensure that non-target tissues are given doses *as low as reasonably practicable* and that the equipment selected for treatment should be appropriate. It is a requirement that every exposure is clinically *evaluated* (see Section 2.16)

1.3.3 Employer's procedures

Schedule 1 lists the minimum set of written procedures that *employers* are required to define, but the *employer* may define other procedures in addition to these. In radiotherapy, there must be procedures to ensure that:

- Patients are correctly identified
- Their pregnancy status is established
- Quality assurance programmes are in place
- The dose is assessed
- Exposures are evaluated and recorded.

Procedures are required to ensure that the probability and magnitude of accidental or unintended doses are minimised. *Practitioners* and *operators* are required to follow the defined procedures ***(Regulation 5)***. *Operators* must identify the patient and ensure that the exposure has been justified and authorised ***(Regulation 6)*** before exposing the patient to radiation.

1.3.4 Investigation of errors

IR(ME)R ***(Regulations 2 and 4)*** requires that a human error that leads to an exposure *much greater than intended* must be reported to the *responsible authority*; that is,

- The Healthcare Commission in England[1,8]
- The National Assembly for Wales[1]
- The Scottish Ministers in Scotland[1]
- The Department of Health, Social Services and Public Safety in Northern Ireland.[9]

This is in parallel to the requirement in IRR that such unintended exposures that are caused by equipment failures are reported to the Health and Safety Executive and the Medicines and Healthcare products Regulatory Agency (MHRA)[10] under its adverse incident notification system.

The *responsible authority* may investigate such errors (and potentially prosecute individuals or *employers* in the event that the error resulted from a breach of the regulations). IR(ME)R does not define *much greater than intended*, although the DH guidance[3] referred to the guidance issued under IRR[7] (see Section 5.3). A course of radiotherapy may not be compromised by a significant error (even 20%) in a single fraction and it is accepted that for this purpose the course should be treated as a whole.

Errors in positioning of the beam may be as significant as errors in the magnitude of the dose and where they have a potential impact on treatment outcome, should also be reported. As the requirement for reporting of exposures *much greater than intended* derives from a regulatory framework designed to protect against the hazards of ionising radiation, there is no requirement for reporting underdoses under IR(ME)R, even though they may also compromise treatment outcome.

Notifications are required whenever the trigger levels are met which are described on the DH website.

1.3.5 Training

The requirement for staff to be adequately trained is as much an important part of the regulations as it is of the European Council Medical Exposures Directive.[4] Comprehensive records of staff training must be kept in association with the list of *practitioners* and *operators* ***(Regulation 11)***. A list of topics that training must cover is in ***Schedule 2***. While the *employer* is required to maintain training records, ***Regulation 11*** also places a duty on the *practitioner* and *operator* not to carry out an exposure without adequate training. The regulations make clear that adequate training refers specifically to the items listed in ***Schedule 2 (Regulation 2)*** and that an appropriate certificate issued by an institute approved to issue degrees or diplomas constitutes sufficient evidence of such training, provided that this is stated on the certificate. This implies that the training referred to is generic rather than specific to an individual department. It is, however, essential that training should be provided to operate the specific equipment (see Appendices 1 and 2, pages 44 and 45).

1.3.6 Equipment

The *employer* is required to draw up a list of equipment held which should include information about the manufacturer, serial number and year of manufacture and installation ***(Regulation 10)***. There is a requirement that the equipment is limited to the amount necessary, implying that superseded equipment must be decommissioned.

2 Duties and definitions

2.1 Who is the *employer*?

The definition in IR(ME)R states, '"*employer" means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation*'.

It is important to recognise that *employer* within IR(ME)R relates to health and safety functions rather than employment matters. The *employer*, as a duty holder under IR(ME)R, is responsible for providing a framework within which professionals undertake their functions. This framework is created through written procedures, written protocols and quality assurance programmes. The *employer* has a statutory duty to make sure these are in place.

The *employer* should be considered to be the chief executive unless an alternative individual has been formally designated as the *employer*. The individual undertaking the role of the *employer* must hold a senior position within the organisation, usually at board level. The individual's role must relate to all those professional groups that provide elements of the radiotherapy service and ideally should incorporate all other services using ionising radiation such as radiology and nuclear medicine. It is usual for the detailed implementation of IR(ME)R to be delegated to an appropriate professional.

2.2 The *employer's* responsibilities

The duties of the *employer* are set out in ***Regulation 4*** and are mainly self-explanatory. Under IR(ME)R, the *employer* is legally responsible, when establishing practices for the safe delivery of radiotherapy, for ensuring that robust procedures exist including those listed in ***Schedule 1, (Regulation (4(1))***. It is essential that procedures are regularly reviewed and updated.

Such procedures must be documented and define how every exposure is *justified* and *optimised*, as well as defining the responsibilities of every individual involved in the process. The individual who is the *employer* must identify who is *entitled* (*entitled* means given permission to act/authorised to act by the *employer* [see Section 1.3.1]) to act as a *referrer*, *practitioner* and *operator* and take steps to ensure that all *practitioners* and *operators* comply with written procedures. The *employer* also has responsibility for putting referral criteria in place and making sure these are available to *referrers*. In radiotherapy, these guidelines are commonly developed as cancer network protocols and multidisciplinary (MDT) patient pathways, supplemented by local departmental protocols for urgent and palliative patients.

Referral for radiotherapy requires a suitably competent individual to assess all the available patient information against any referral criteria and they must be *entitled* by the *employer* to make that decision. The *employer* should also recognise that referral criteria cannot be written for every clinical situation and *entitle* suitably knowledgeable individuals to refer for radiotherapy in those cases. It might be appropriate to limit this to consultant staff.

Additionally, the *employer* is responsible for:

- Having a quality assurance programme in place – ***Regulation (4(3b))*** (see Section 4.2, 4.3)
- For establishing dose constraints for research – ***Regulation (4(3d))*** (see Section 4.4, 4.5)
- For ensuring that *practitioners* and *operators* are adequately trained – ***Regulation (4(4))*** (see Section 2.3, 2.4)
- For investigating and reporting incidents where a dose *much greater than intended* has been delivered to a patient – ***Regulation (4(5))*** (see Sections 5.1–5.11).

All of these issues are covered in more depth later in this document.

2.3 The *employer's* responsibilities for training

The *employer* has a responsibility to ensure that all *entitled practitioners* and *operators* are adequately trained to perform the tasks in their defined scope of practice ***(Regulation 4((4)a and (4) b))*** and similarly *practitioners* and *operators* shall not *carry out a medical exposure or any practical aspect without having been adequately trained.* ***(Regulation 11(1))***

'*The employer shall keep and have available for inspection by the appropriate authority an up-to-date record of all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures … showing the date or dates on which training qualifying as adequate training was completed and the nature of the training.*' ***Regulation 11(4)***

Adequate training to achieve and maintain professional registration is determined by the relevant regulatory body as defined in the National Health Service Reform and Healthcare Professions Act 2002.[11] For the purposes of demonstrating adequate

training to be a duty holder in radiotherapy under IR(ME)R, this training needs to have specifically covered training in radiation safety issues for radiotherapy.

Non-registered healthcare staff can be *entitled* to act as *operators*, such as radiotherapy assistant practitioners (APs), who have trained on a Society and College of Radiographers' (SCoR) approved course, and some trainees in other disciplines who have received radiation specific training, but this may not be the case for all staff such as some clinical technologists. The *employer* will need to address any additional training needs before entitling these staff to act as *operators*.

For all *practitioners* and *operators*, this initial training should only be considered as a starting point rather than an endpoint in demonstrating adequate training within a local department. Responsibility for ensuring that adequate and up-to-date local training is delivered and recorded, rests with the *employer* and must be consistent with the tasks the individual is *entitled* to carry out.

When an *employer* identifies a member of senior staff as having responsibility for IR(ME)R documentation, assessment of staff competence and maintaining training records then the *employer* must ensure that this individual's employment contract gives sufficient time and resources to discharge this responsibility.

2.4 Training records to be kept for inspection

As individuals join a department, there is often a period of induction into local procedure. Training thereafter is continuous, as part of continuing professional development (CPD) and in response to the introduction of new equipment, new techniques or as upgrades to operating software and systems of work occur.

For this reason, training records need to reflect this continuous development and local department-specific training, as well as that achieved through additional external qualifications and courses.

Practitioner training records

Professional qualifications in clinical oncology (for example, Fellowship of The Royal College of Radiologists [FRCR] by examination and the subsequent award of a completion of specialist training certificate [CCST] by the Postgraduate Medical Education and Training Board [PMETB]) are suitable for use as evidence of competence to act as a *practitioner* for a defined scope of treatment and concomitant exposures. This scope of practice needs to be specified in local documentation. This may be further guided by recognition of site specialisation and entitlement should be appropriate to the skills and up-to-date training and experience of the individual as this duty carries a legal responsibility under IR(ME)R.

Registered healthcare professionals who are not medically qualified can be *entitled* by their *employer* to act as *practitioners* for a defined scope of practice; for example, *justification* of concomitant images or palliative radiotherapy. In a similar way, their formal professional training may be used as evidence of the training necessary to carry out such roles,[12–14] but this will need to be reviewed on an individual basis. It is necessary that this formal training includes the benefits versus detriment of exposure to ionising radiation. Consideration should be given locally to any additional training or experience required, relevant to the pre-registration training and the imaging and treatment modalities in use. An example of how to demonstrate *practitioner* entitlement and training is shown in Appendix 1, page 44.

As verification imaging is a developing area of practice, the *employer* must ensure that all those individuals justifying such exposures have received adequate up-to-date training and are competent, before *entitling* them to act in this capacity; for example, when introducing cone-beam computed tomography (CT) on the linear accelerator, where the benefit versus detriment of the radiation exposure will be different to that inherent in 2-D portal imaging. This can be achieved by offering in-house or external training.

There is a requirement for additional training and documentation for both medical and non-medical staff as new technologies are implemented. This will require assessment on an individual basis.

Further information is available in a future publication on verification by The Royal College of Radiologists in conjunction with the Society and College of Radiographers and the Institute of Physics and Engineering in Medicine.[15]

Operator training records

The *employer* must have documented and up-to-date evidence of training. Training records for physicists and radiographers to undertake *operator* tasks (that is, *practical aspects* of the *exposure*) are often well developed and up to date, reflecting

training and competency achieved as they learn different skills. This is often not the case for clinical oncologists who also undertake *practical aspects* such as the use of computer planning and virtual simulation software, positioning of brachytherapy applicators and evaluation of images, including verification images. Good practice requires that training in local departmental practice should be documented in an overview of training records for all professional groups.

To simplify writing procedures and avoid lengthy descriptions about different staff groups at different levels of training having to be defined in such procedures, it can be helpful to include a statement such as in Example 1.

Example 1.

Treatment planning can only be carried out by an adequately trained, *entitled operator*. A trainee can undertake treatment planning under direct supervision of an *entitled operator* who is responsible for the task being completed correctly.

An up-to-date matrix of all treatment planning techniques and tasks and those *entitled operators* is held and maintained by the head of the radiotherapy treatment planning section.

2.5 If I change jobs, how will my new employer know what I have been trained to do?

Accredited training such as the FRCR and the qualifications required to achieve the status of registered healthcare professional will be straightforward when moving to another *employer*.

Training for specialist registrars in clinical oncology often rotates between different cancer centres, but within the same training scheme. It would therefore be appropriate for evidence of training – in a form recognised as suitable for inclusion in their personal training portfolio – to be reviewed by a designated clinical oncologist on behalf of the *employer*. They can then be *entitled* to undertake a defined *practitioner* role (for example, certain palliative treatments in and out of working hours). It would also be appropriate for evidence of core training to be agreed within a rotation, and for the individual trust's IR(ME)R documentation to reflect this.

Many individuals are required, as part of their continued registration to practice, to demonstrate CPD. This will also assist a new *employer* to assess training and to determine the scope of practice for which the individual can be *entitled*.

It is more difficult and, particularly for those individuals who do not have to be a registered healthcare professional, to demonstrate local additional and equipment-specific training.

It is, therefore, advisable to obtain copies of any *employer's* training records before moving on. Although these may be in a different format from those of the new *employer*, they will provide a foundation to establish what an individual is trained to do and what additional training might be required. This is particularly relevant if an individual is expected to extend their scope of practice and take an additional responsibility in the new post.

2.6 What is meant by a *referrer*?

The *referrer* must be a *registered healthcare professional* as defined in IR(ME)R (see Section 3.14).

Referrers are *entitled* by the *employer* to request that a patient is exposed to ionising radiation as part of the whole treatment process.

The *employer* should specify the scope of practice for which an individual can refer. This may be limited to referral for planning, referral for treatment, referral for verification images or be any combination of the three. It is important to make this distinction in written procedures. This can often best be demonstrated by using a table similar to that shown in Table 1, Appendix 1, page 44.

Confusion has arisen in the past because the term 'referral' is well understood in the context of one healthcare professional requesting that a colleague takes forward the management of a patient based on either a confirmed or suspected diagnosis. The date that this type of referral is received is collected routinely for waiting times data.

In practice, an appointment is made for a patient to see a clinical oncologist or a member of a site-specific multidisciplinary team (MDT) for an opinion on the management of the patient. If, as the result of such an appointment, the patient requires

radiotherapy treatment, a radiotherapy request or booking form will be completed or this information will be entered into the patient's notes. This request for a patient to be exposed to ionising radiation constitutes a *referral* in the context of IR(ME)R.

2.7 Information required for a referral

IR(ME)R requires that the *referrer* provides the necessary information to the *practitioner*.

'*The referrer shall supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the medical exposure requested by the referrer to enable the practitioner to decide on whether there is a sufficient net benefit as required by* ***Regulation 6(1)(a).***'

A referral must be made by a *registered healthcare professional* as defined by IR(ME)R. *Referrers* are *entitled* by the *employer* to request that a patient is exposed to ionising radiation as part of the treatment process. It is essential that the *referrer* provides sufficient clinical data so that the exposure can be *justified*. For a radiotherapy treatment referral, this means details, as appropriate, of:

- Diagnosis
- Histology
- Clinical finding and staging examinations must be made available.

It is not safe to rely on second-hand information, and the source documents or copies should be available throughout the radiotherapy process, particularly at critical points such as planning and prescription as these data are essential for *justification*.

For referral for additional planning or verification images, the *employer* should define the referral criteria and what clinical information is required from the *referrer*.

How a *referrer* carries this out and documents this at all parts in the radiotherapy pathway should be described in written procedures.

2.8 What is meant by a *practitioner*?

IR(ME)R states that the *practitioner* must be a registered healthcare professional and that *the practitioner and operator should comply with the employer's written procedures.* ***(Regulation 5(1))***

The *practitioner* is *entitled* by the *employer* to *justify* and *authorise* (see Section 2.14) the exposure of a patient to ionising radiation as part of the whole treatment process. To do this, the request for the exposure is assessed against the clinical data supplied by the *referrer*. The *practitioner* must have adequate training and be competent to weigh up the potential detriment of the exposure against the potential benefits for that individual (see Section 2.9). This judgement should take into account all the associated risks including the risk of second cancer induction from concomitant exposures and the likelihood that such exposures will improve the accuracy of treatment and so reduce side-effects. The possibility of alternative treatment and verification techniques, including perhaps a technique which does not use ionising radiation, should also be considered.

In radiotherapy, the *referrer* and *practitioner* for a course of treatment may be the same person and *entitled* to undertake both functions (for example, a consultant filling in a radiotherapy action sheet at a multidisciplinary meeting). Nevertheless, it should be emphasised that these are two distinct parts of the process by which a patient comes to be exposed and that the requirements of both functions must be met. This should be made clear in the *employer's* written procedures. It may be appropriate to require two separate signatures to provide evidence of *referral* and of *justification*, but the need for this will depend on the requirements of the specific procedures.

The *employer* should specify the scope of practice for which an individual can act as a *practitioner*. The scope of practice may be limited, for example, to *justification* of planning exposures or to additional verification exposures on treatment or to any combination including treatment itself. It is important to make this distinction in written procedures and this can often be best demonstrated using a table (Appendix 2, page 45). *Practitioners shall not carry out a medical exposure or any practical aspect without having been adequately trained.* ***(Regulation 11(1))***

It is also the *practitioner's* responsibility to ensure that the treatment is individually planned and that the dose to non-target tissues is as low as reasonably practicable – although this does not mean that the *practitioner* personally needs to carry out the treatment plan. ***(Regulation 7(2))***

2.9 What is *justification*?

Justification is the process of weighing up the potential benefit of the exposure against the potential detriment for that individual. This judgement should take into account the probability that the requested exposures will achieve the desired outcome and whether different exposures, using a different technique or another dose would be suitable instead. Account must also be taken of the possibility of using techniques which do not use ionising radiation which can be addressed at the tumour-specific multidisciplinary team meeting.

In justifying therapy doses, it is important to consider possible alternative treatments which do not use radiotherapy. For instance, in stage I testicular seminoma which has a 15% risk of relapse, options include:

- Risk stratification and surveillance of lower risk patients with CT scans[16]
- Para-aortic radiotherapy which has been used in this role for about 50 years. There is a large amount of late follow-up data, indicating a 1.4-fold increase in the relative risk of second cancer. At 30 years' follow-up, when patients are approaching 60 years of age, cancer incidence in the untreated population is 17%. In the irradiated population it is 25%. This represents an absolute increase of 8% in cancer incidence[17]
- Carboplatin – this treatment with a single dose of chemotherapy has been shown to reduce relapse rate to 4% (the same as radiotherapy); follow-up data are limited and there are few long-term results.[18]

Another example of an alternative management strategy would be in the management of carcinoma of the cervix: patients with early-stage disease can be treated with radiotherapy or with radical surgery. For most patients, the latter is the best option as there are fewer long-term side-effects and no increased risk of a second malignancy.[19]

2.10 Detriments to be considered in justifying an exposure

The detriments to be considered include long-term and short-term side-effects and these must be weighed against the benefit and also must be compared with other approaches not using ionising radiation. For radiotherapy treatment, these issues form an important part of the consent process. (It should be noted that consent is not within IR(ME) regulations.)

There is a very long list of acute medium-term and long-term side-effects with which staff should be fully familiar from their training. Of particular concern are the long-term hazards of infertility, about which patients should be counselled before treatment. It is extremely important to try to avoid accidental irradiation of pregnant patients due to the risk of affecting organogenesis. Detailed planning and dosimetry are required to justify the intentional irradiation of a pregnant patient.[20]

The other major long-term hazard is of carcinogenesis. The risks vary with the part of the body irradiated and with the dose. In addition, some patients may have a genetic predisposition to carcinogenesis by radiotherapy and it is believed that this may be implicated in the very high risk of breast cancer in young women who received radiotherapy for Hodgkin's disease.[21] Another example of a high-risk group is children with neurofibromatosis type I who are at an inherent high risk of secondary cancer which can be increased by radiotherapy.[22] There is also an increased risk of radiation-induced vasculopathy[23] and intellectual deterioration.[22] These considerations lead to chemotherapy being the firstline treatment strategy for low-grade malignancy of all central nervous system sites for children with neurofibromatosis type 1.

Most radiotherapy patients in the UK are treated for malignancies but some are still treated for benign disease and these require careful consideration.

Children and young people are more sensitive to the carcinogenic risks of radiotherapy,[21, 24] with children being ten times as sensitive as older patients. They will therefore require special consideration.

Calculation of lifetime risk is complicated but there have been publications which attempt to address this issue.[25]

Training will also be required in the communication of these issues to patients to enable consent.[26]

The practice of medicine always involves assessing risk and benefit. Radiotherapy is for many patients an effective and appropriate curative or palliative anti-cancer treatment.

2.11 What is the core of knowledge?

Core of knowledge was a term identified in the previous Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations (POPUMET) which were revoked in ***Regulation 14*** of IR(ME)R and replaced by ***Schedule 2***.

The core of knowledge training provided education such that the use of radiation in medical exposures would be soundly based.

Under IR(ME)R, the requirement that *practitioners* and *operators* must be adequately trained is guided by information provided in ***Schedule 2*** of the Regulations.

The ***Schedule*** outlines subjects which need to be addressed with regard to theoretical knowledge (including regulatory requirements) and practical experience:

(a) Relevant to their functions as *practitioners* or *operators*

(b) Relevant to the specific area of practice.

The intentions of both POPUMET and IR(ME)R were to cover those professionals who wished to undertake medical exposures but would not consider this to be their primary function and therefore would not have received theoretical knowledge and practical experience as part of their formal training. An example of this would be an orthopaedic surgeon who wished to undertake exposures to guide a surgical procedure.

For radiotherapy, the requirements of ***Schedule 2*** are largely addressed by specific professional qualifications and experience. The exception to this may be where individuals undertake functions associated with role development and extension, in which case the contents of ***Schedule 2*** must be addressed and evidence of this should be available before *entitlement* is extended.

2.12 What is meant by an *operator*?

The *operator* does **not** have to be a *registered healthcare professional*. The definition of *operator* is stated in IR(ME)R as *any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects*.

The *employer* should specify the scope of practice and the tasks for which an individual can act as an *operator* and be able to demonstrate they are adequately trained to undertake these tasks. Using a matrix is a simple way to demonstrate this, as shown in Appendix 2. Individual training records for *operators* require regular updating as individuals develop, and equipment and techniques are constantly changing. It is important to include clinical oncologists as *entitled operators* for the *practical aspects* they carry out such as elements of computer planning.

Written procedures could then include statements such as in Example 2.

Example 2

Radiotherapy treatment must be delivered by an *entitled operator* (see training matrix). The *operator* initiating the exposure is responsible for ..... and will sign in column A on the treatment sheet. Outlining of the GTV must be carried out by an *entitled operator* (see training matrix).

Regulation 5(1) states, *The practitioner and operator should comply with the employer's written procedures.*

Regulation 11 states that, *No practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained.*

2.13 Are service engineers or in-house equipment technicians classed as *operators*?

Operators are duty holders who are *entitled* to carry out *practical aspects* of a *medical exposure. Practical aspects* include the physical conduct of the exposure and other supporting aspects that have a direct influence on radiation dose to the patient.

The non-statutory guidance[2] on *operators* states that, *Third-party service engineers would not normally be considered as operators. Where significant changes to equipment have been made, these should be checked where practicable by an operator (for example, an employee of the NHS trust) before equipment is brought into clinical use.*

In most circumstances in radiotherapy, third-party engineers, whether providing initial installation or servicing, are responsible for presenting a machine in a safe condition, but they are not responsible for the equipment being in a state fit for clinical use. Following initial installation or service, third-party engineers will release to the NHS trust equipment that conforms to specification and will demonstrate this by presenting data on performance, logs of servicing undertaken and so on, but further measurements and verification are needed before the equipment can be used clinically. It follows, therefore,

that the third-party engineers have undertaken work that will be checked before equipment is used to make *medical exposures* and therefore the work of third-party engineers cannot be considered to directly influence *practical aspects* of an exposure and therefore they are not considered as *operators*.

Further measurements are then undertaken by in-house clinical technologists, physicists or by those who are responsible, as *entitled* by the employer (in this example the NHS trust) for presenting or returning the equipment in a state fit for clinical use. These staff collect, provide or verify data that are used directly in calculation and delivery of treatment to patients. As such, they are providing supporting aspects to the medical exposure that directly influence the radiation dose to patients and are therefore *operators* under IR(ME)R.

2.14 What is meant by *authorisation*?

Authorisation is not formally defined in the Regulations. ***Regulation 6(1)(a)*** requires that all exposures be *justified* by the *practitioner*. In addition, ***Regulation 6(1)(b)*** requires that no person shall carry out a medical exposure unless it has been *authorised* by the *practitioner* or by an *operator*. ***Regulation 6(5)*** permits an *operator* to *authorise* an exposure '*in accordance with guidelines issued by the practitioner*' if the *practitioner* is unable to do so. ***Regulation 6(5)*** has a limited value in radiotherapy and is unlikely to be used often in the justification of therapeutic exposures, although it is widely used for verification imaging and for correction protocols.

Authorisation is the verification that the process of *justification* has taken place and is usually demonstrated by the signature of the *practitioner* or *operator* as allowed above. *Justification* itself is an intellectual process (see Section 2.9).

2.15 What is meant by *optimisation*?

Regulation 7 describes the requirements for *optimisation* of exposures. *Optimisation* in this sense is one of the three basic principles of radiological protection (justification, optimisation and dose limits) and is defined by the International Commission on Radiological Protection as the 'process to keep the magnitude of individual doses … as low as reasonably achievable below the appropriate dose constraints, economic and social factors being taken into account'.[24]

Thus, *optimisation* in radiotherapy includes ensuring that:

- Exposures of target volumes are individually planned ensuring that doses to non-target tissues are as low as *reasonably practicable* while achieving the intended radiotherapeutic purpose of the exposure
- The equipment used is appropriate to minimise any unnecessary dose
- Adequate quality assurance is in place
- Patients involved in research are fully informed and *dose constraints* associated with the research are adhered to
- A clinical *evaluation* of the outcome of each exposure is recorded.

Regulation 7 requires that particular attention is paid to *medical exposures* of children, pregnant women and breastfeeding women (in the case of radionuclide therapy).

It may be regarded as a reasonable interpretation of this Regulation that wherever possible non-target normal tissues should be shielded as in conformal therapy.

2.16 What is meant by clinical *evaluation*?

The requirement that a *clinical evaluation of the outcome* of all exposures must be recorded ***(Regulation 7(8))*** is included within the *optimisation* requirements and is primarily designed to prevent unnecessary exposures being made in the diagnostic context. If an exposure is not to be *evaluated* then it cannot be *justified* and therefore should not be made.

The decisions made following clinical *evaluation* should be consistent with safe and effective practice guidance.

Radiotherapy includes a range of medical exposures and the purposes of clinical *evaluation* for each of these – including medical exposures relating to planning, verification and treatment – are different. The *evaluation* must be carried out by an adequately trained *operator* who may be a clinician but could also be a non-medical *operator,* such as a therapeutic radiographer (as is often the case with portal images).

Planning exposures

The *evaluation* of planning exposures is demonstrated by their use. Such exposures are either fit for purpose or not. The CT dataset or orthogonal images used should be identifiable from records. Audit of planning exposures that are deemed not to be fit for purpose should inform future processes and training needs. This should result in reduction of unnecessary exposures for future patients.

Pretreatment verification

The *evaluation* of these exposures is essential to demonstrate that the intended therapy can be delivered as prescribed. For these exposures, the diagnostic quality of the image produced is a secondary consideration.

On-treatment verification

Portal images and kV images taken during treatment must be *evaluated* for correctness and this check documented by *entitled operators* as part of a written procedure. For these exposures, the quality of the image produced is a factor. These *evaluations* will provide the basis for adjustment or continuation of treatment and must therefore be carried out in a timely manner.

Treatment

Regular clinical reviews should be conducted while the patient is on treatment by *entitled* adequately trained staff. At the conclusion of treatment, an end-of-treatment summary provides a clinical *evaluation* of the radiotherapy course. As a minimum, the *evaluation* should record the delivered treatment dose and any reasons why this differs from that intended. Immediate clinical effects, for example, a skin reaction, should be included as part of the *evaluation*.

2.17 The roles of the radiation protection advisor and the *medical physics expert* under IR(ME)R

The radiation protection advisor (RPA) has no statutory responsibility under IR(ME)R.

The *medical physics expert* (MPE) is defined in IR(ME)R 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*'. ***Regulation 9*** requires that the MPE must be '*closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices*'. The role of the MPE is further defined as '*consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practices*'.

Therefore, from the statutory point of view, any issue that arises from matters covered by IR(ME)R are the province of the MPE and anything arising under IRR[7] is the province of the RPA. One area where there is clear overlap is in the quality assurance of radiotherapy equipment which is a requirement of both sets of Regulations. In practice, it is common for the RPA to be an independent clinical scientist who provides advice on an occasional basis, whereas the MPE is fully involved in the work of the radiotherapy department. It is important to note that, in contrast to the MPE, the RPA is not expected under the terms of either legislation to be actively involved in doing the work and therefore has a more restricted remit.

There is, however, no reason why the two roles should not be performed by the same individual, but when this happens it is advisable that advice given in the capacity of RPA is clearly identified as such.

2.18 The role of individuals who are not *registered healthcare professionals* such as radiotherapy assistant practitioners and clinical technologists in practical aspects of the exposure. What supervision and training should be available?

Qualified clinical technologists and qualified radiotherapy assistant practitioners are not registered with any regulatory body (such as the HPC) but are trained to carry out specific practical aspects of radiotherapy and as such can be *entitled operators* for those aspects. A voluntary register of clinical technologists is currently in place and may in future be incorporated under the HPC.

Before entitling a clinical technologist or a radiotherapy assistant practitioner to act as an IR(ME)R *operator,* the *employer* must ensure that the person is adequately trained and that the training meets the requirements of ***Schedule 2*** of the Regulations. The scope of such entitlement should be clearly documented. Similar considerations could apply to other staff groups where specific training is applied. Training should be given and documented for the tasks an individual will be *entitled* to undertake.

The role of the radiotherapy assistant practitioner has been developed as part of the Society and College of Radiographers four-tier structure of assistant practitioner, practitioner, advanced practitioner and consultant. Further guidance is available in *Education and Professional Development: Moving Ahead* by the Society and College of Radiographers.[27] It is important to note that the use of the title 'practitioner' in this context differs from the use of the title '*practitioner*' under IR(ME)R. Radiotherapy assistant practitioner education courses approved by the Society and College of Radiographers include the fundamental principles of medical radiation generation, interaction, modification and protection as defined in ***Schedule 2*** of the Regulations.[3] Further guidance is available in *The Learning and Development Framework for Clinical Imaging and Oncology* by the Society and College of Radiographers.[12]

The level of supervision required to be given to a radiotherapy assistant practitioner will depend on local circumstances and will be influenced by the *entitled* scope of practice and competence of the individual (see Section 2.19).

2.19 What is meant by *supervision*? Does this imply a physical presence?

When an *operator* task is being undertaken 'under supervision', the supervisor is fully responsible as *operator* for that task.

The situation in which the supervised person is already competent to carry out the task but is nevertheless not an *entitled operator* requires less supervision than a trainee who has never carried out the task before. In the latter case, 'direct' supervision is appropriate with the supervisor constantly present and watching what is being done. More 'indirect' supervision would be appropriate in the former situation, and the supervisor might consider it appropriate to simply check what has been done after it is complete. However, if, for example, a complex plan is being done it may be difficult to ensure that the plan has been carried out correctly by examination of the finished product and closer supervision will therefore be necessary. A student therapeutic radiographer or trainee assistant practitioner who is not trained in a specific aspect cannot act on their own and needs direct supervision and cannot be an *operator*. However, an assistant practitioner who is fully trained and qualified in a specific aspect can act on their own and can be an *operator* but should have someone available to them to provide advice and act in a supervisory capacity and available in such a way that the supervisor can, for example, influence the exposure in a timeframe consistent with the clinical episode.

It is essential that the supervisor has agreed to oversee a particular piece of work before the work commences, and that the supervisee is clear who is supervising them. Since the supervisor is taking full responsibility for the work once it is complete, the supervisor has the right to dictate the level of supervision required. However, if the competence of the supervisee has been formally assessed, it is reasonable for the supervisor to rely on that assessment as valid. If a particular action will have an immediate effect on a patient (such as turning on the radiation beam), direct supervision is always required.

Where a person carrying out the task is considered fully competent to do so it is normally appropriate that they should be authorised to act as an *operator* in their own right, rather than relying on a supervisor.

Although radiotherapy assistant practitioners operate professionally under the supervision of an HPC-registered therapeutic radiographer, when these individuals are acting as *entitled* IR(ME)R *operators*, they are legally responsible for their actions. Further guidance is available in *The Scope of Practice of Assistant Practitioners in Radiotherapy* by the Society and College of Radiographers[28] and *Breaking the Mould: Roles, Responsibilities and Skills Mix in Departments of Clinical Oncology* by The Royal College of Radiologists.[14]

2.20 What is necessary to satisfy the requirement for *procedures for the assessment of patient dose and administered activity*?

A radiotherapy department will have many procedures relating to the assessment of patient dose such as procedures which deal with the preparation of treatment plans and the calibration of linacs and sealed and unsealed sources. The use of *in vivo* dosimetry is another method for the assessment of patient dose and procedures relating to this should also be included. For simulators and CT scanners, a record should be kept of the exposure factors and volume parameters which affect radiation dose.

2.21 Are *diagnostic reference levels* necessary for treatment planning exposures?

IR(ME)R requires that *diagnostic reference levels* (DRLs) are established for radio-diagnostic examinations. The purpose of radiotherapy planning exposures is not diagnosis and they are not therefore required for these exposures. However, as stated in the Medical and Dental Guidance Notes Section 8.87, 'the general principle of as low as reasonably practicable must still be applied'.[2] Records of all simulation exposures should be maintained in order to demonstrate this principle.

3 Responsibility

3.1 The difference between 'professional' and 'legal' responsibility under IR(ME)R

Radiotherapy is a complex process that involves a range of professional activities and functions, most of which have a direct impact on the safe delivery of ionising radiation to the patient.

Under IR(ME)R, these functions are largely carried out by duty holders and it is essential that duty holders are identifiable and accountable. Failing to act appropriately as a duty holder may result in enforcement action under criminal law.

Regulation 4(1) states, *The employer shall ensure that written procedures … are in place*. These include procedures that provide the scope of entitlement of professionals as duty holders and the way in which such duty holders should proceed to carry out those tasks.

Regulation 5(1) states, *The practitioner and the operator shall comply with the employer's written procedures*.

Regulation 11 states that, *No practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained*.

An individual duty holder's legal responsibility is to act in the way the *employer* has set out in written procedures. An individual's professional responsibility is to:

- Have and express a professional view, where appropriate, as to whether those procedures are adequately designed to ensure safe delivery of radiotherapy treatment to a patient
- Be able to challenge the actions and decisions, as appropriate, of others if their performance is likely to result in ineffective or unsafe delivery of radiotherapy treatment to a patient. It is the valued professional role of any healthcare professional to look beyond their traditionally defined boundaries to improve care for patients.

If any member of staff considers that treatment is unsafe or unsatisfactory they have a responsibility to bring this to the attention of a senior colleague such as the radiotherapy services manager, head of radiotherapy physics or clinical lead.

Exercising professional responsibility and challenging a situation should be encouraged. Doing so can avert serious adverse events. The confidence to challenge outside one's own professional activities often comes from a 'feel' for a situation. An example might be the questioning of a monitor unit value that exceeds by a considerable margin the normal values used for a particular set-up. The person identifying the potential error should not proceed with treatment, but should bring the potential error to the attention of those with the responsibility for calculation. It is a professional responsibility, rather than a duty under IR(ME)R, to be constantly alert to the possibility of an error from any source and ensure that non-conformances are raised within the quality management system (see Section 3.5).

3.2 What constitutes a prescription? What does a signature on a prescription mean a *practitioner* is responsible for?

The potential therapeutic effects and the detriment the exposure may cause are influenced not just by the dose and fractionation, but also the volume of tissue irradiated, dose to critical structures, modality and energy of radiation and treatment delivery and verification techniques.

Therefore, the act of prescribing combines an overall appreciation of the reasons, risks and benefits of radiotherapy in that individual patient with technical details of the optimal administration.

In *justifying* the exposures and prescribing the treatment, the *practitioner* needs to take into account the following factors set out in ***Regulation 6(2)***.

(a) The specific objectives of the exposure and the characteristics of the individual involved

(b) The total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure

(c) The individual detriment that the exposure may cause

(d) The efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

All exposures must be *justified* and *authorised* before they are made and the signed prescription is the evidence of *authorisation* that treatment can proceed.

Written procedures should clearly define that a signature on a radiotherapy prescription sheet means that the *practitioner* has *justified* the treatment and is *authorising* it to proceed. Without this clarity, there can often be differing opinions among staff in a department about what the signature on a treatment prescription sheet means. It is not acceptable for one individual to take responsibility for the treatment dose on the prescription sheet and a second individual to take responsibility for the volume to be treated as this would imply that the responsibility for *justification* is shared.

It is possible to delegate the task of *authorisation* to someone competent to undertake this; the *practitioner* retains responsibility. All or some of the tasks of marking up the gross tumour volume (GTV), clinical target volume (CTV), and planning target volume (PTV), outlining critical structures and generating a computerised treatment plan may be delegated to an entitled *operator*, but there should be a clear statement about who is responsible for these elements being correct. In this case, the *operator* is responsible for the task being carried out correctly and does not deviate from an agreed, issued protocol.

A protocol should be written in such a way that sufficient information is specified about the volume for treatment, margins, and maximum doses to non-target tissues, such that an entitled *operator* following the protocol can unambiguously satisfy the conditions of the *practitioner's* prescription. In this case, the prescription should identify the protocol to be used, so that an *entitled operator* can *authorise* the plan to be used. It should be emphasised that the use of this concept should be restricted to simple techniques where the requirements of the treatment plan can be met without compromise.

So, if the planning requirements have been adequately specified by a *practitioner*, an *entitled operator* could authorise the 3D-dose distribution against such specifications.

Regulation 7(2) requires that the *practitioner* ensures that radiotherapeutic exposures are *individually planned* and that the dose to non-target tissue is *as low as reasonably practicable*. Unless detailed procedures are in place to ensure that this is the case, this would imply that the *practitioner* must verify that the plan is appropriate in this respect before treatment proceeds.

If such a protocol does not exist then the *practitioner* must *authorise* the plan before use.

3.3 If I am asked to sign something, what is the legal significance of this and how do I know that this is appropriate under IR(ME)R?

Your signature means you are taking responsibility for that specific part of the radiotherapy process. It would be inappropriate to sign for something outside your control, for which you have not been trained and that you do not have the tools to complete.

The text in Example 3 is a good example of an excerpt from a procedure.

Example 3

The *operator* who switches the machine on should check that the energy, wedge, gantry, collimator, monitor units displayed on the treatment unit are consistent with those on the defined source document (eg, treatment plan) before switching the machine on. They should sign in column 'A' of the treatment sheet to indicate they have done so.

The *operator* is not being asked to check that the values are correct. It is neither possible nor appropriate for this to be done at the treatment console; responsibility for this rests further back in the process.

Written procedures should explicitly state which duty holder is responsible for an element of the process and this responsibility should not be passed forwards but remain with the entitled individual. When an element is completed, the next person to take the process forward should be able to see that the previous element was completed and who the responsible duty holder was. Unless they are specifically checking something is correct; such as a calculation, they should not be responsible for what someone else has done. Nevertheless, all duty holders under IR(ME)R also have a professional responsibility to raise concerns about steps in the radiotherapy treatment process which seem to be incorrect.

3.4 The implications of one clinician signing another clinician's plan

It is not uncommon in a busy department for more than one clinical oncologist to carry out different tasks during the preparation of a patient's treatment and this is also an important part of training, but there can only be one *practitioner* for an exposure.

As discussed in Section 3.2, a clearly defined written procedure setting out what constitutes a prescription and what the *practitioner* signing the prescription is taking responsibility for, allows individuals who also contribute to the planning tasks to be clear about what they are responsible for and what the *practitioner* is responsible for.

For example, one clinician performs part of the planning process (such as prescribing) and another clinician accepts the dosimetry and *authorises* the plan against a protocol so that the patient can proceed to treatment. In this situation, the clinical oncologist who is *authorising* the plan for use is acting as an *operator.*

In these circumstances, the responsibility for all the elements of the prescription being correct still rests with the *practitioner.* In simple standard techniques, the specification of the plan requirements by the *practitioner* may be sufficient to allow the *authorisation* of the treatment plan to be carried out by an *operator* following a clearly defined protocol. However, in other situations where balancing the risks and benefits of treatment may require modification of the treatment plan, only a *practitioner* can approve the plan. Procedures should clarify these issues for particular situations.

3.5 Clinical oncologists may feel that they are entirely responsible for the whole care of the patient. Is this correct under IR(ME)R?

Professional staff often feel a responsibility for functions that are outside their control. In medicine, it is acknowledged that the medical care of a patient is led by staff of consultant status. The clinical oncologist, therefore, often feels responsible for all the things which happen to a patient during their course of radiotherapy. While they have a professional and general medico-legal responsibility for the medical management of the patient and for which tasks they delegate to other staff within the specific context of the medical exposure, they cannot be held legally responsible under IR(ME)R for each and every task undertaken by other duty holders.

Staff should be clear that they are legally responsible under IR(ME)R for those duties which their *employer* has *entitled* them to undertake. *Practitioners* and *operators* should have received adequate training and should therefore be competent to undertake the task. They must not carry out duties or take responsibilities that they are not *entitled* to undertake.

All of the above does not detract from the professional and medico-legal responsibilities that individuals have (see Section 3.1).

3.6 Can you delegate a task while retaining responsibility?

Under British law, responsibility cannot be delegated, an individual is either responsible or not. However, an individual can delegate a task to another individual – as long as that individual is competent to undertake the task – and still retain responsibility. This means that that work must be overseen, reviewed or checked and must be signed for by the person responsible.

This approach is possible under IR(ME)R and there are many examples of how this might provide a practicable way of working (see Example 4).

Example 4

The task of outlining the organs at risk (OAR) can be delegated to another individual such as a trained dosimetrist but a written procedure can specify that the *practitioner* who prescribes the treatment takes responsibility for the prescription, including the volume to be treated and the dose to be delivered to the target and the OAR. The *practitioner* should review the plan including the treatment volume and the OAR to confirm their accuracy. Under this approach, if the OAR were incorrectly delineated, the *practitioner* would be responsible under IR(ME)R.

OR

Responsibility for the outlining could alternatively be transferred to the *operator.* The *practitioner* could specify the treatment prescription against a protocol which defines a margin around the organ to be treated, the dose to which this should be treated and the tolerable doses that might be received by the OAR. The dosimetrist, as an *operator* who was appropriately trained to identify and delineate the treatment volume and the OAR, would then proceed to do so. In this case, the dosimetrist becomes responsible under IR(ME)R for the correct placement of the structure outlines.

But before deciding upon these arrangements, alternative approaches should be considered and the one least likely to produce errors and confusion over responsibilities should be selected. As a rule, where a function can be allocated to a duty holder, and responsibility appropriately allocated, this should be preferred to delegation of the task.

In each case, the *practitioner* would need to be satisfied as to the competence of the dosimetrist. If the dosimetrist is to be an *operator*, and responsible therefore for the accuracy of the outlining, that individual must be *entitled* by the *employer* who has ensured they are adequately trained to carry out the task, and that the method of carrying out the task was defined in a written procedure.

Unnecessary delegation has been identified as a known cause of error and should be avoided; for example, when treating a patient it is best practice to identify them yourself rather than delegate. This has been identified as a cause of error in a number of reports.

3.7 Do I have to ask every female patient if they are pregnant?

The phrase used in ***Regulation 7(7(e))*** is '*where appropriate*' and in ***Regulation 6(1(e))*** is '*if relevant*'. So for instance, the local procedure for completing referral data could incorporate the requirement for medical information about likely fertility where relevant. Discretion about when an *operator* should then ask this question of patients could be defined in a protocol.

So if the intention is to palliate symptoms of advanced disease in a young woman rendered infertile by chemotherapy, then local protocols could reflect the way to act in this situation; for example, the responsible clinician signing to say that questioning regarding fertility is not appropriate.

3.8 Who should *justify* images in centres where verification images involve additional radiation?

Exposures that will always be carried out as part of a particular treatment procedure should logically be taken into consideration when the treatment as a whole is *justified*.

The imaging exposures are then *justified* by the *practitioner* who prescribes the treatment as part of a defined set of verification exposures for particular techniques prior to treatment commencing. This element should also be included in any definition of a prescription.

However, it should be noted that there must be a maximum number of exposures stated or reference made to an authorised protocol of verification exposures. The *practitioner* is assessing the benefit versus detriment of the radiation exposure and therefore this cannot be open-ended.

Any verification imaging protocol should also be signed off by an *entitled practitioner*. It is good practice for this to be done by a consultant who it is agreed will lead in this particular area: they should seek input from clinical colleagues about appropriate site or technique-specific imaging. However, this does not represent the *justification* of an individual patient exposure that is required by IR(ME)R.

If it is practice for *justification* of verification exposures to be carried out at a different time or by a different *entitled practitioner*, there should be a separate written procedure for this process.

If additional images are required other than those set out in the imaging protocol, a procedure must be in place specifying how *justification* is carried out and where it is documented.

The *employer* must define the scope of imaging procedures for those staff *entitled* to act as *practitioners* for verification exposures, in line with their training, particularly as technology develops in this area.

3.9 What is the role of countersigners under IR(ME)R? Is this different from the countersignature culture evident in Cancer Standards (England)?

Under IR(ME)R, the individual signing to take responsibility must be *adequately trained* and *entitled* by the employer. If they are not *entitled* by the employer to undertake functions as an IR(ME)R duty holder then they should not sign to indicate they are taking responsibility under IR(ME)R.

Provided that responsibilities are clearly defined in written procedures, this is not inconsistent with the Cancer Standards[29] in England which state the use of countersignatures is appropriate at certain times. However, procedures must be framed such that there is unambiguous identification of the accountable duty holder.

Where specialist registrars, those developing into extended roles and others in training carry out tasks as a part of their learning, it is common practice to indicate they have done so by initialling or signing somewhere. This must then be checked by an *entitled* duty holder who must sign to indicate that they are taking responsibility under IR(ME)R.

It is essential that written procedures address the issue of signatures that do not identify *entitled* duty holders. Such signatures should be placed in brackets or in a separate 'completed by' section of the documentation.

Example 5

A specialist registrar in training completes a radiotherapy prescription for a palliative treatment but has not yet been *entitled* by the *employer* to act as a *practitioner*. In this case, the consultant does need to personally verify the data and sign to indicate they are the responsible duty holder under IR(ME)R. There is a need to identify who did something even if they did so in training. If the trainee places their initials in brackets, they can be identified.

It is best to avoid the use of countersignatures wherever possible as this limits the possibilities for confusion over who is the responsible duty holder.

It is advisable to have lists or matrices available, indicating scope of entitlement and ideally sample signatures and initials of staff. This can help in verifying the appropriate duty holder signing to take responsibility under IR(ME)R.

Example 6

The specialist registrar in training is entitled by the *employer* to act as a *referrer* for radiotherapy, including pretreatment exposures, and has access to referral criteria from the *employer*. The procedure for completion of referral forms will specify that all relevant medical data must be available to the *referrer* for this task; eg, notes, pathology, images and so on. The source data will also be required later in the radiotherapy process (see 2.7). The *referrer* completes, signs and dates the form in the '*referrer*' section consistent with the responsibilities defined in the written procedure.

Although the referral has been made by an *entitled referrer*, the exposures must be separately *justified* and *authorised* by an *entitled practitioner*.

Example 7

The consultant or another registered healthcare professional is entitled by the employer to act as a *practitioner* and *justify* exposures based on the medical data supplied by the *referrer*. What constitutes *sufficient medical data* should be defined in the procedure. It is unsatisfactory to make decisions about justifying a course of radiotherapy without these data available.

The *practitioner* reviews the data and the details on the request form, decides that the proposed exposures are justified and signs and dates a '*practitioner*' section on the form. The *practitioner* takes responsibility for the *justification* and *authorisation* but not for the referral details being correct.

The *practitioner*, if they so choose, can decide the requested exposures are not justified and different exposures would be more appropriate, in which case they record this change and sign and date it.

They may decide that no exposures are justified and therefore do not authorise the request.

This outlines the legal responsibilities under IR(ME)R. The professional responsibility for the medical management of the patient still rests with the consultant.

For clarity, the above examples have been based on the traditional consultant/registrar roles. Skills mix is to be encouraged and the principles are applicable to non-medical extended practice in all disciplines.

3.10 How should referral for concomitant exposures additional to those documented in an original referral be made?

A referral is a request for an exposure, not a direction to undertake an exposure. All referrals must be *justified* by a *practitioner* before an exposure takes place.

The common approaches in use throughout the UK to refer a patient for concomitant exposures are:

- The referral for pretreatment, treatment and verification exposures is carried out by a clinical oncologist or other *entitled registered healthcare professional*
- Exposures are defined in a verification imaging protocol. *Registered healthcare professionals* are then *entitled* to refer patients for additional verification or re-simulation exposures if there are patient set-up or technical problems
- *Registered healthcare professionals* are *entitled* by the *employer* to refer patients for a defined scope of concomitant exposures.

Whichever approach is adopted locally, the following should be defined in written procedures.

- All staff acting as *referrers* must be *entitled* to act in this capacity by the *employer*. ***(Schedule 1b)*** The scope of exposures for which they can refer should be defined.
- *Referrers* must be aware of their responsibility to supply the *practitioner* with sufficient clinical data for the exposure to be justified. ***(Regulation 5(5))***
- The *employer* must have referral criteria in place. ***(Regulation 4(3a))***
- The *referrer* must be informed of how and where to document the referral and this will vary depending on what the referral is for. They must sign and date the referral.

Example 8

If a patient has lost all their set-up marks they can be referred for re-simulation.

If, during treatment, a change is made to the isocentre position relative to the reference tattoo, the patient should be referred for a verification image to confirm the move has been made as specified.

It is important to remember that a *referrer* does not require training under IR(ME)R but they must be *entitled* by the *employer* and must operate within a defined scope of practice.

3.11 Who should *justify* pretreatment and concomitant exposures?

Regulations 6 (1a & b)) require that all exposures are *justified* and *authorised* before they are made.

Justification requires the *practitioner* to assess the benefit versus detriment from the exposure in the context of appropriate disease management, balanced against long-term risk to normal tissue and induction of secondary malignancy.

The *justification* of treatment exposures is well understood and the *practitioner* for such exposures is the individual who accepts responsibility for the prescription.

In the case of pretreatment images *justification* is less well understood.

It is standard practice for the prescription to be completed after the planning has taken place, following definition of the treatment volume and the assessment of dose to adjacent critical structures. Where this is the case, the *practitioner* signing the prescription cannot also be responsible for *justifying* and *authorising* the pretreatment exposures and complying with IR(ME)R.

Documented *authorisation* must be provided prior to planning exposures being made. This can be achieved by having a separate box 'Justified and authorised by' on the radiotherapy request form which is signed by the *practitioner*.

It must be remembered that the task carried out by the *practitioner* is different from that of the *referrer*. Although it is routine for many individuals to be *entitled* to act as both *referrer* and *practitioner*, there should be an identifiable individual for each action, either in the way a procedure is drafted or by having two separate signature boxes on the form.

As practice and roles change within radiotherapy, an *employer* may decide to *entitle* some other *registered healthcare professionals*, in line with published professional guidance,[14] to act as *practitioners* for a limited scope of practice. The *employer* must be able to demonstrate that such individuals are adequately trained. To act as a *practitioner*, an individual must be able to demonstrate an understanding of the benefit and any possible detriment in the context of the radiation exposure to that individual.

Example 9 shows situations where non-medical staff might be *entitled* to act as *practitioners*.

Example 9

- **A patient with breast cancer is referred for adjuvant radiotherapy from the MDT by a specialist nurse. The pretreatment exposures are *justified* by an *entitled* radiographer who works in pretreatment. The prescription for treatment is completed by a consultant.**
- **Adequately trained staff can be *entitled* to act as *practitioners* for verification images additional to those in an agreed protocol.**
- **Adequately trained staff can be entitled to act as *practitioners* justifying simulation, re-simulation or palliative planning exposures. They would sign the relevant section on a referral (request) form.**

Written procedures should be in place defining the scope of practice and stating clearly where the *practitioner* should document *authorisation*.

3.12 Can you have multiple *operators* performing elements of one defined task but only one of them taking responsibility?

Where several staff are involved in a particular task, the *employer* must define in written procedures whether they all have equal legal responsibility or whether one person is acting as the responsible *operator* for the purpose. This decision should be taken based on local conditions, including:

- Staff numbers
- Training, experience and skill mix
- Standard and non-standard treatment techniques
- Frequency of use and complexity of techniques.

Where multiple people share responsibility, it must be made clear that they are all equally and fully responsible. Alternatively, specific aspects of the process may be defined and responsibilities assigned individually.

Whichever approach is adopted, it must be clearly defined in a written procedure and there should be a description of how the *operator(s)* indicate they were the responsible duty holder(s).

- If it is the responsibility of one *operator*, define which signature column(s) they complete if there are two on a treatment sheet.
- Specify signature or initials.
- Consider using unique electronic passwords.

Phrases such as 'the radiographers are responsible for' should be avoided as this does not define which duty holder is responsible.

3.13 Is it necessary to define what is meant when using the term 'checking'?

When using the word 'check' in a written procedure, it needs to be expanded to define exactly what is meant and what an individual is required to do and what responsibility they have. Equally, this will define what responsibility other individuals have taken throughout the process. The *employer* should seek to place responsibility appropriately and not ask individuals to check things they are not trained to check or for which they do not have the necessary data or equipment to check.

The written procedure should define whether the duty holder is expected to:

- Establish whether certain tasks have been undertaken and signed for prior to proceeding to the next step
- Confirm consistency of data with an identified source document following transcription or data entry
- Check whether something is correct; for example, performing a calculation using different data or a different methodology to test the accuracy of the result.

When checking something is correct, you should always seek to find ways to carry out a process in a different way to maximise the chance of identifying an error. This is because, as discussed in the joint report on the *Balancing Costs and Benefits of Checking in Radiotherapy,*[30] the first person carrying out a task is more likely to do it correctly than a second person is likely to pick up an error during checking. Calculations can be checked by carrying out the calculation in a different way.

In the *employer's* IR(ME)R procedures it is, however, important to identify who has the responsibility to ensure that a particular check has been carried out before treatment. The procedures should define a series of checks that need to be

carried out before treatment is initiated. If the *operator* who initiates treatment does so without evidence of a check being completed, they are then held responsible if it has not been. *Operators* treating patients are inevitably under time pressure and it is not reasonable to expect them to look through a number of different documents at this time. Systems should be in place to ensure that patients do not arrive for treatment when the checking of their data is not complete.

However, such systems can fail and it is recommended that there is a very clear indication that all the checks have been carried out. If such a system is in place and there is a clear flag showing that checks are complete, the treating radiographer should be expected to check that the flag is set. However, documentation should make it clear that the setting of the flag is not part of the treating radiographer's duties.

3.14 The role of the multidisciplinary team (MDT) in referral for radiotherapy

This is related to Section 2.6.

A referral must be made by a *registered healthcare professional*. Referrals come via a number of routes including the MDT, follow-ups in clinic, ward rounds and so on. The *employer* must set out referral criteria and *entitle* individuals to act as *referrers* for radiotherapy for a defined scope of practice.

All exposures must be justified by an *entitled practitioner* with the appropriate training in radiation oncology (Example 10).

Example 10

A medical oncologist or orthopaedic surgeon could complete a referral for radiotherapy following specific referral guidelines. This information must then be reviewed and exposure to ionising radiation must be *justified* before simulation and treatment.

This is the minimum requirement under IR(ME)R, but good practice is that a clinical oncologist is involved in the MDT and where referrals do not come directly from clinical oncologists then local procedures should state that only a clinical oncologist *practitioner* can justify the requested exposure, prior to any planning or treatment.

3.15 What should be included in a patient identification procedure?

Schedule 1a requires the *employer* to have in place a procedure to *identify correctly the individual to be exposed to ionising radiation*. This should be consistent across an organisation and should be developed in line with national guidance from the DH and NPSA.

Any such procedure should state the method for carrying this out and cover all patient states, including as a minimum:

- Outpatients
- Inpatients
- Children
- Blind
- Deaf
- Mute or non-English speaking patients
- Those unable to identify themselves who may have a carer with them
- The unconscious patient.

This should not be considered an exhaustive list.

The patient should actively respond to questions and the source document, against which the responses are checked, must be stated in the written procedure. It is usual to ask for three identifiers, typically, name, address and date of birth. Some Record & Verify (R&V) systems allow a patient photograph to be saved in the record or use barcode systems. How technology can assist in the process should be regularly reviewed and incorporation considered where possible. The publication *Towards Safer Radiotherapy* has important guidance on this subject.[31]

Procedures should also indicate how the correct electronic record is identified at all stages in the process from imaging through to treatment.

Errors have occurred because the wrong electronic data set has been used to treat a patient.[31]

The patient identification procedure should state what to do if the patient cannot be identified using one of the methods specified in the procedure or if different identifiers are inconsistent.

Identification should be carried out at every attendance prior to any exposure taking place and the procedure should state how an *operator* indicates they have completed this task; for example, a signature on the simulator set-up sheet, the treatment sheet or using an electronic *operator*-unique password in the R&V system.

Where two signatures are recorded, the procedure should state clearly if one or both *operators* are responsible and, where applicable, state which individual *operator* is responsible for patient identification being correct; for example, 'the *operator* responsible for the patient being identified correctly should sign in column 'A' on the treatment sheet'.

3.16 What is meant by Regulation 7(7(b)) which states that *the practitioner and operator shall pay special attention to medical exposure of children*?

Paediatric radiotherapy practice is a highly specialised area and the indications for treatment should be guided by national and international protocols. Treatment should be given in a recognised children's cancer and leukaemia group (CCLG) radiotherapy centre except on rare occasions when palliative radiotherapy can appropriately be given more locally to the patient's home.

Children are at much greater risk of carcinogenesis both from therapy and imaging exposures.[21, 24] *Justification* and *optimisation* of such exposures should be undertaken by individuals with appropriate specialist training and competence and should not be treated as routine (see Section 2.10).

3.17 What is my responsibility for patient care when I am away from work?

When you are not at work, clarity about ongoing responsibility is essential. Clearly, you cannot provide active care for a patient, but general professional and legal responsibilities for a patient continue to be assigned to a consultant in their absence. For example, if a consultant has *justified* a course of radiotherapy, the individual exposures may be undertaken in the consultant's absence and the consultant remains legally responsible for decisions made earlier. This is consistent with the legal view that responsibility cannot be delegated, but remains with the duty holder. Tasks can be delegated as long as the person to whom the task is delegated is competent.

During planned absence, it is in incumbent on all staff to ensure that arrangements have been made to ensure that patient care continues uninterrupted and that any problems that arise can be efficiently dealt with by someone else. This may be achieved by the transfer of responsibility or delegation of tasks.

It is essential to hand over any outstanding tasks to a clearly identified, named, *entitled* individual to minimise the risk of miscommunication. For medical staff, it is essential that planning procedures or prescriptions do not proceed on the assumption that the results of any outstanding investigations will be as expected. There must be a fail-safe mechanism to ensure that patients receive appropriate treatment.

If planning procedures are incomplete and the legal responsibility for the work is to be transferred to another individual, that individual must be adequately trained and *entitled* by the *employer* to undertake the *practitioner* role for that site specialty. It must be quite clear that they are then accepting the responsibility of *justification*. This will involve reviewing the work done by the absent *practitioner* to approve it before signing the final prescription to *authorise* treatment (see Sections 3.3 and 3.4). It is useful to all staff to clarify the arrangements in writing.

Similar issues arise in the event of sudden unexpected absence and departments must establish clear governance arrangements to deal with such contingencies.

3.18 What arrangements are appropriate for the prescription of radiotherapy for emergencies out of hours?

The arrangements for *justifying* and *authorising* radiotherapy exposures for out-of-hours emergencies should be as robust as those in place during the normal working day. If a single fraction is incorrectly planned and subsequently altered, then the patient has received a suboptimal treatment. If a dose *much greater than intended* has been delivered to target or non-target tissues then this may be reportable under ***Regulation 4(5)***.

Suitable arrangements must be made for the planning of emergency radiotherapy. This may involve simulation, CT simulation or portal imaging on set before treatment. Clinical mark-up without radiological verification will only rarely be appropriate and the reasons should be recorded in the patient's notes.

If treatment is to be requested and prescribed by an on-call trainee or radiographer, they must be *entitled* by the *employer* to act as a *referrer* and *practitioner* for both planning and treatment exposures. In both routine and emergency settings, this means that they are competent to plan and prescribe the treatment.

If the trainee or radiographer is not both competent and *entitled* to take responsibility as a *practitioner* for planning and treatment exposures then it is incumbent upon the supervising consultant to attend the hospital to undertake the planning and prescribing to ensure delivery of satisfactory treatment which can be *justified* under IR(ME)R. Responsibility cannot be delegated to non-entitled staff, nor can the treatment volume be *optimised* without seeing the treatment plan or set-up.

Alternatively, the planning exposures could be *justified* by a competent trainee or radiographer who has been *entitled* to take this responsibility as *practitioner*. The planned treatment volume images could be reviewed and approved remotely by the consultant. If a protocol for emergency prescribing exists, the trainee or radiographer could be *entitled* as an *operator* to *authorise* treatment exposures if all the criteria in the protocol were met. The protocol should have been signed off by an *entitled practitioner*, who retains legal responsibility for *justification* under IR(ME)R.

3.19 What are my responsibilities if I discover an error?

When you discover an error it is essential that it is reported in accordance with the *employer's* procedures.

When the error has occurred in the planning process and has not resulted in an incorrect treatment to the patient then the treatment plan can be corrected. If erroneous treatment has been delivered to the patient then there must be an internal investigation by the *employer* to determine whether the incident is reportable to the IR(ME)R inspectorate under ***Regulation 4(5)*** (see Section 5.3).

If an incorrect treatment has been delivered, it will be incumbent on the treating clinician to consider the implications for the patient and how any further treatment should be adjusted to compensate for the error. In such circumstances a review of the proposed compensatory action by a second consultant clinical oncologist is advisable; additional advice from a person with an interest in error corrections may be necessary.[32] The patient should usually be informed of what has happened, how it occurred, what the implications are for their treatment and the risk of side effects. They may also wish to know what can be done to prevent a repetition. Detailed advice is given in the recent publication *Towards Safer Radiotherapy*.[31] Specialised professional advice can be sought through the professional organisations.

4 Procedures, protocols and auditing

4.1 How should procedures and protocols be managed?

The *employer* is responsible for ensuring that written procedures, including those in ***Schedule 1***, and protocols for every standard type of radiological practice for all equipment are in place.

A good procedure will make it clear that a specific individual (rather than a professional group) has responsibility at every point of the radiotherapy process.

A system of version control should ensure that protocols are kept current and only the correct version is in use. The protocol should be readily accessible to all staff groups and the development of protocols should be a two-way process reflecting developing practice. Documentation of training is core to IR(ME)R.

Example 11 shows an example of version control and responsibility

Example 11. Issuing process for radiotherapy handbook

A programme for the review of the radiotherapy handbook is set out annually in October. The lead clinician is responsible for ensuring that this programme is in place.

Sections are reviewed regularly by the monthly meeting of the Radiotherapy Clinical Governance Group. These meetings are chaired by the lead clinician who has responsibility for ensuring that the review programme is adhered to. All radiotherapy consultants and registrars are invited to attend the meeting and at least two members of each group must be present for a quorum. A senior radiotherapy clinical scientist and a superintendent radiographer must also be present.

Suggested changes arising from the meeting are made to master copies of the Word documents by the radiotherapy secretary who sends the altered chapters electronically to the lead clinician. The lead clinician circulates the suggested new chapter to all relevant staff and collates feedback.

Formal approval of the new chapter is carried out at the next meeting of the Clinical Governance Group and this approval is recorded electronically by the lead clinician. The document is then issued on the intranet by the Quality Management Representative.

Examples of clear matrices are shown in Tables 1 and 2 in Appendix 2, pages 45 and 46.

Other points to note

Consistent relevant terminology should be used in all written documentation; for example, consistent use of either radiotherapist or clinical oncologist in written procedures to describe the medical staff.

All source documents against which 'checks' should be made should be identified in the documentation.

4.2 What is meant by quality assurance?

Schedule 1e requires the *employer* to have procedures in place *to ensure that quality assurance programmes are followed.*

At the beginning of IR(ME)R, quality assurance is defined as *Any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and safely complying with agreed standards and includes quality control.*

'*Quality control' means the set of operations (programming, co-ordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of performance.*

The required quality assurance programme should cover all aspects of the process of planning and treatment of patients and should include any steps necessary to ensure safe treatment. To ensure that the quality assurance programme is being followed, a system of regular audits is essential. These requirements are likely to be fully met by an ISO9001 quality system,[33] but as discussed in Section 4.3 such a system is not an essential requirement.

Any quality assurance programme also needs to cover the written procedures as defined in IR(ME)R ***Regulation 4(1)***, which will be those listed as addressing ***Schedule 1***, and written protocols for standard radiological practice for each piece of equipment ***(Regulation 4(2)).***

To demonstrate compliance with ***Schedule 1e***, the *employer* should have in place a procedure which states:

- Which written procedures will be reviewed
- How often
- What the review will entail
- Which individual is responsible for the review being completed
- How they demonstrate it has been done.

The *employer* is free to decide on the frequency of review of written procedures but should take into account the impact changes in technology and staff role development have on ways of working when deciding timescales.

4.3 The relationship between a quality system and IR(ME)R

Compliance with IR(ME)R is a statutory requirement and it is the responsibility of the *employer* to ensure that there is a set of written procedures in place to which the duty holders must then adhere. A quality management system can help compliance with IR(ME)R, but it must be clear which parts of the documents are intended to form part of the IR(ME)R procedures. Failure to follow these procedures could be deemed to be a breach of compliance with legislation.

IR(ME)R requires that there should be a *quality assurance programme for standard operating procedures*, ***(Regulation 4(3) b)*** but there is no legal requirement that the programme should be subject to external review or certification (for example, under ISO9001[33]) by an accredited body although this is highly desirable (and is required by the Cancer Standards).[29] However, there are parallels between IR(ME)R and a quality standard.

IR(ME)R 2000

- Health and safety legislation
- Aims to prevent harm to patients from misuse of ionising radiation during medical diagnosis or treatment
- Sets the minimum standard to prevent malpractice
- Subject to internal audit and external inspection
- Enforceable by criminal law.

Quality management system (QMS)

- International standard quality management systems such as ISO 9001[33] require the quality assurance of product and also aims to enhance customer satisfaction
- ISO9001 1.1a specifies requirements for a quality management system where an organisation needs to demonstrate its ability to consistently provide products that meets customer and applicable regulatory requirements[33]
- ISO 9001 7.2.1c requires the organisation to determine statutory and regulatory requirements related to the product[33]
- Quality systems are subject to internal and external audit
- Quality systems are not legally enforceable – but highly desirable.

The majority of UK radiotherapy departments were operating under a quality framework prior to IR(ME)R. To avoid repetition, many institutions chose to adapt their quality documents in radiotherapy to demonstrate compliance with IR(ME)R. Failure to understand the distinctions has been the cause of some difficulties.

Where the decision has been taken to demonstrate compliance with legislation within the documents that form part of the quality system, the *employer* should recognise that this changes the status of such documents from being desirable to an essential tool to demonstrate legal compliance and they need to ensure that sufficient resources are in place to maintain these documents to satisfy legal requirements.

Adaptation of quality documents has not always been successful. Two particular issues should be addressed when considering the appropriateness of existing quality documentation.

- The *employer* is responsible for implementing IR(ME)R consistently throughout the organisation – not just in radiotherapy – and, in many cases, a separate organisation-wide document has been produced to achieve this. Care needs to be taken that this does not contradict statements in local radiotherapy procedures, thus leading to confusion

and ambiguity. For example, where definitions of *referrers* and *practitioners* differ between radiotherapy and diagnostic radiology, this should be specifically stated.

- Quality standards written before 2000 often contained statements such as 'clinical oncologists are responsible for ...'. They should be reworded to make it clear which specific clinical oncologist is responsible for particular functions. It is also necessary to make clear in what capacity that responsibility is being exercised. Thus, the broad statement above would become more specific as, 'The clinical oncologist who signs the prescription is responsible as *practitioner* for the *justification* of the treatment exposure and for ensuring that the treatment plan has been *optimised*'.

It is desirable that the responsible duty holder who has undertaken a task or function should be identifiable from written procedures and the relevant patient records. IR(ME)R seeks to identify the responsible duty holder who has undertaken a task or function and for them to be identifiable from a written procedure and the relevant documentation (see Example 12).

Example 12

The referrer must complete all sections on the front of the radiotherapy booking form and sign the referrer box, putting the date and their contact number.

OR

At simulation, the operator who exposes the patient to ionising radiation is responsible for the patient being identified correctly and will sign box X on the simulation sheet.

4.4 The implications for research of implementing IR(ME)R in radiotherapy

IR(ME)R does not inhibit research but does require that certain issues are addressed, which are stated in ***Regulation 7***.

(4) For each medical or biomedical research programme falling within Regulation 3(d), the employer's procedures shall provide that:

(a) The individuals concerned participate voluntarily in the research programme

(b) The individuals concerned are informed in advance about the risks of the exposure

(c) The dose constraint set down in the employer's procedures for individuals for whom no direct medical benefit is expected from the exposure is adhered to

(d) Individual target levels of doses are planned by the practitioner for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a diagnostic or therapeutic benefit.

These issues are addressed in guidance[34] published in December 2006 by the Central Office of Research Ethics Committees (now the National Research Ethics Service [NRES] as of April 2007).

For a multicentre study, there should be an identified lead clinical radiation expert and a lead *medical physics expert*, so that when central ethical approval is given any local ethics groups can obtain clear guidance on the radiation issues as presented to the approval body. It is not expected that the local process duplicates the work done by the leads.

It may not be practicable to have a global *constraint* in place covering all research protocols. The requirement of IR(ME)R in this respect will be met provided that for each research study there is a clear written *constraint* on the additional dose delivered for research purposes.

4.5 Where do responsibilities lie when patients are treated in research studies?

IR(ME)R requires that the *employer* establishes *dose constraints* for exposures made for research purposes where there is *no direct medical benefit* to the patient ***(Regulation 4(3)d)***, and such exposures must be referred to a Research Ethics Committee ***(Regulation 6(1)c)***. ***Regulation 7(4)*** requires that there is fully informed consent and that dose constraints are adhered to. Where there is expected to be benefit to the patient, *individual target levels of dose* must be established by the *practitioner.*

The National Research Ethics Service – NRES (formerly the Central Office for Research Ethics Committees – COREC) has issued guidelines (*Approval for Research Involving Ionising Radiation*[34]) on how research should be authorised. For national studies, the chief investigator (CI) is responsible for getting ethics approval for the study from the main Research Ethics

Committee (REC) for the trial. Where the CI is not qualified to act as a *practitioner*, a clinical radiation expert (CRE) must be appointed to advise on the justification of the exposures involved in the study. These issues must be considered in collaboration with a medical physics expert (MPE). Together they are required to consider the differences between standard practice at the participating centres.

Each participating centre must identify a principal investigator (PI) who is responsible for the local management of the study. If the PI is not *entitled* to act as *practitioner* for all exposures in the study, the PI must identify a *practitioner* for these exposures. The *practitioner* and MPE must consider any differences that exist between the local situation and the assumptions of the national study so that the CI can be informed of these. For example, it may be that standard local practice is to treat a particular cancer surgically or to use a different dose fractionation schedule. The PI is responsible for submission of the study to the local REC who must consider any local differences and inform the main REC that the local centre is considered suitable to enter patients. The *entitled practitioner(s)* must confirm in writing to the local PI and the local Research Governance office that:

- The local centre is able to adhere to the protocol
- Where local patients would receive additional exposure, this has been identified in the main REC application and has been ethically approved by the main REC
- Any additional exposure is justified with regard to IR(ME)R.

Although justification of the exposures has been fully considered in this way, there is nevertheless a requirement for individual justification of the exposures by the *practitioner* responsible for the treatment of the patient. However, it is legitimate for the *practitioner* to take into consideration the ethical discussions that have already taken place in regard to the general patients, but any circumstances relating to the individual patient must also be considered.

Where a study involves the research use of radionuclides (that is, if radionuclides will be used in the research study in any way that differs from routine clinical practice), it is also necessary that a Research Certificate is in place from the Administration of Radioactive Substances Advisory Committee (ARSAC). However, where the use of radionuclides is routine management, the ordinary ARSAC certificate is sufficient.

5 Inspection and reporting of incidents

5.1 Responsibility for enforcement of IR(ME)R

IR(ME)R is made as a Statutory Instrument under the Health and Safety at Work etc. Act 1974.[6] This means that the Regulations form part of health and safety legislation and are thus criminal legislation.

Enforcement of the legislation is carried out by *the appropriate authority*; defined in IR(ME)R as *the Secretary of State as regards England, the National Assembly for Wales as regards Wales, or the Scottish Ministers as regards Scotland* and whose powers are set out under the Health and Safety at Work etc. Act 1974.[6]

Each *appropriate authority* has an appointed inspector(s) who has the power to carry out proactive inspections of any facility where ionising radiation is being used for medical purposes to assess compliance with IR(ME)R. The inspector will carry a warrant and has powers to enter the premises at a reasonable time and take with them anyone else authorised by their authority to assist them. They can investigate, see and take samples of articles they think relevant and can require anyone whom they believe able to give information, to do so.

In the event of an incident being reported or where the inspector believes there is a 'situation which in his opinion is or may be dangerous', the same powers apply.[6]

As health is a devolved government function, there is a different *appropriate authority* for each of the four administrative areas in the UK.

- **England:** Healthcare Commission
- **Scotland:** Scottish Ministers, Scottish Executive Health Department
- **Wales:** National Assembly for Wales: Health and Social Care Scientific Division.
- **Northern Ireland** has its own regulations and defined *appropriate authority*.[9]

5.2 What sort of inspections can the *appropriate authorities* undertake?

Reactive inspection is an escalation in response to a notification of an incident or from concerns raised by the public or whistleblowers.

Proactive inspection is consistent with a proportionate risk-based approach to regulation.

A checklist to help prepare for a proactive inspection is available at Appendix 3, page 47.

IR(ME)R is enforced under the Health and Safety at Work etc. Act (1972).[6] In the event that the inspector identifies a significant breach of the Regulations, they have the power to issue an improvement notice requiring that the problem is rectified within a specified time. In the extremely unlikely event of a very serious breach or of failure to address an improvement notice, there is also the power to shut down the facility.

In England, the Healthcare Commission is required to carry out proactive assessment of high-risk services, such as radiotherapy departments twice in each five-year period.

5.3 The requirements to report under IR(ME)R

Employers are obliged under ***Regulation 4(5)*** to investigate where an incident has occurred or may have occurred in which a person has been *exposed to ionising radiation to an extent much greater than intended*.

Unless the *preliminary investigation* shows that *no such overexposure has occurred*, then the *appropriate authority* must be notified and the *employer* must *make or arrange for a detailed investigation of the circumstances of exposure and an assessment of dose received*.

Non-statutory guidance on the definition of the term *much greater than intended* has been prepared by Department of Health and is published on its website.[3]

Because any guidance published is non-statutory, the decision of whether to report an incident must be taken by the *employer*. However, it is strongly recommended that in cases of doubt a report is made.

5.4 Notifying the *appropriate authority* and the information they want in an initial report

The details of how to contact the *appropriate authorities* are listed in Appendix 4, page 49.

In an initial notification of an incident, the following information should be included:

- Date of the incident
- Age and sex of the patient
- What happened, what dose should have been delivered in what fractionation and what dose was delivered, with an indication of the number fractions on which the error occurred
- What is the potential for harm, both short- and long-term adverse effects, to the patient as a result of the incident
- Has the patient been informed
- What medical and non-medical support is being made available to the patient
- Why the incident happened
- Whether procedures were followed
- What is being done to minimise the risk of the incident occurring again.

Notification should include contact details of an individual who the inspector can liaise with for further information or to arrange meetings. Such an individual should have a managerial position in the department involved, to ensure the correct information is made available to the inspector or to ensure the appropriate people are available to attend any meetings.

Note. Any notifications should not include information which could identify the patient.

5.5 How is a notification dealt with?

Similar approaches are adopted by all inspectors to the one set out below for the Healthcare Commission (HCC) in England.

When the HCC is notified, notifications are received by the IR(ME)R notifications officer or the IR(ME)R co-ordinator and an acknowledgement sent to the person lodging the report.

The assessor for the establishment in question also receives a copy of the notification for their information.

A file is raised for each notification in which all subsequent process, correspondence and decisions are recorded.

Initial triage is by the IR(ME)R lead inspector. Subsequent steps are covered in Section 5.6.

5.6 The possible outcomes of a notification

At the HCC, all incidents are recorded and assessed against a risk matrix which leads to three possible outcomes.

- Additional information requested – queries on a notification are likely to be by email or telephone.
- No further action – when the file on a notification is 'closed', this is always in writing to the chief executive of the organisation with a copy to the notifying person.
- Decision to undertake an investigation which can lead to a reactive inspection.

The HCC has already modified its notification 'web form' to increase the number of data items required, in order for it to be able to provide better feedback to the professional community in reports such as that published in March 2008 describing its activities since assuming enforcement responsibilities in November 2006.[35]

5.7 The possible outcomes of an investigation which leads to a reactive inspection

Following an initial investigation, the inspector may decide that a reactive inspection should be carried out.

Under the powers of the warrant the inspector holds, they can question the individuals involved in the incident and any other individuals who may be able to provide relevant information. This can take the form of either a witness statement or a statement under caution.[36]

Any individual is able to take a colleague, friend, legal or professional representative with them if they are asked to answer questions by the inspector as part of a reactive inspection.

Before asking any questions, the inspector will make clear whether an individual is being questioned as a witness or under caution.

A verbatim record will be taken of the questions and answers and the inspector and the respondent will either sign the record at the time or, if the conversation is taped, the tapes are sealed and signed by both before the respondent leaves.

5.8 Reporting of incidents that do not fit the IR(ME)R notification criteria

There is no statutory requirement to report to the *appropriate authority* any incident which does not fit into the definition. However, there is now a system in England and Wales to report all incidents to the National Patient Safety Agency (NPSA) as part of the clinical governance process.

Departments are advised to collect data on all incidents and near misses, analyse the causes of such incidents and employ resources and strategies to reduce the risk of such errors occurring in the future.

Professional guidance on the management of incidents and errors can be found in the joint publication *Towards Safer Radiotherapy.*[31]

5.9 How does IR(ME)R, written under criminal law, fit with an open reporting culture?

IR(ME)R is designed to ensure patient safety and is enforced under the Health and Safety at Work etc. Act (1974).[6] A breach of the regulations through overdosage (see Section 5.4) is reportable by law to the *responsible authority* (see Section 5.1) and could lead to a criminal prosecution.

This fear of criminal prosecution has generated two adverse effects:

1. Creation of a poor reporting culture

2. Prevention of shared knowledge of reported incidents so reducing the potential for learning from previous errors.

In a specialty with a high public profile when errors occur, albeit as a tiny percentage of all treatments, it is vital that the public is reassured by demonstrating high-quality systems.

Following a significant radiation incident in 1988[37] a quality assurance system for radiotherapy (QART) was produced.[38] This was the first of successive quality systems applied to the complex and multidisciplinary process of radiation treatments, such as ISO 9001[33] and the Healthcare Accreditation and Quality Unit (HAQU).

During this period, clinical governance was established in trusts (or equivalent) to improve the quality of care through setting, delivering and monitoring standards. A pillar of clinical governance is risk reporting and analysis of adverse events, near misses and complaints. This process must then demonstrate learning from them by correction of poor performance and systems.

The effectiveness of these systems is now monitored by the HCC and through consumer audit, via the NPSA. These two bodies work together to reflect and inspect the safety of processes within trusts. Where poor outcomes and systems are shown, improvement notices can be applied to suspend or rapidly improve services implicated.

These measures are applicable to IR(ME)R.

It is expected that feedback of radiation incidents from the Healthcare Commission and the Health Protection Agency will occur in the future to facilitate learning.[31]

It is therefore essential for radiotherapy departments to demonstrate that effective quality systems are in routine practice and that risk reporting is used to learn from errors and near misses.[31] This is essential to enable a defence of *due diligence* in response to a radiation incident (see Section 5.10).

5.10 How do we demonstrate *due diligence* has been exercised to implement IR(ME)R?

In IR(ME)R, there is a specific defence of *due diligence* at ***Regulation 13***. '*In any proceedings against any person for an offence consisting of the contravention of these Regulations it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.*'

As a minimum, the *employer* should ensure that they meet the requirements of ***Schedule 1***.

The *employer* must be satisfied that *entitled* duty holders are adequately trained and competent where necessary.

Duty holders must follow their *employer's* written procedures to demonstrate legal compliance with IR(ME)R. They should also be mindful of their professional responsibility to challenge procedures they consider unfit or unsafe.

Practical ways of demonstrating that all reasonable steps have been taken include:

- Minutes of multidisciplinary group meetings
- Document control and review
- Clinical audit which can include both outcomes of clinical care and audit of practice
- Participation in national radiotherapy trials and associated quality assurance.

At the level of the individual operator, it is accepted that no one can carry out their tasks without making errors from time to time. (The quality assurance programme should be designed to pick up these errors.) *Due diligence* is shown by adhering to the *procedures* laid down by the *employer*. Failure to follow the *procedures* will make the defence of *due diligence* hard to substantiate. It must be made clear to all members of staff which are the IR(ME)R procedures, and systems should be in place to ensure that staff are fully aware of the requirements of these procedures. *Due diligence* requires, however, that the individual staff member is proactive in ensuring that they read and follow procedures as laid down. If the procedure is considered inadequate it must nevertheless be followed until it is changed. The safety of the patient is paramount. If there is considered to be a possibility of actual harm to the patient, the *practitioner* should be consulted and a record made of the *practitioner's* decision. Treatment should not proceed until staff are reassured that it is correct to do so.

5.11 The implications of legal action under IR(ME)R; where will I seek legal support?

Indemnity cover for individuals under IR(ME)R by trusts (or equivalent) is complex. Radiotherapy departments should check with the risk manager at their trust (or equivalent) whether it is a member of the *Liabilities to Third Parties Scheme* established by the NHS Litigation Authority or a scheme that provides equivalent cover. If not, the risks to which the trust (or equivalent) is exposing not only itself but the all the radiotherapy-related professional staff it employs as regards IR(ME)R should be explained.

Regardless of these arrangements, it would be wise for individuals (including trainees) to have professional indemnity insurance through individual subscription or membership of a professional body which provides this (such as the Society and College of Radiographers).

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Appendix 1. *Entitled referrers* and *practitioners*

Table 1. Staff entitled by ******** NHS trust to act as *referrers* for exposure of patients to ionising radiation as part of the planning or delivery of radiotherapy treatment**

Name	External beam radiotherapy		Brachytherapy		Pretreatment simulation	Pretreatment planning CT scans	KV verification Images	MV verification images	Re-simulation
	Radical	Palliative	Radical	Palliative					

Referrals must be made in line with the criteria set out in [name of document]

The responsibilities of the *referrer* and the procedures for completing referral documents are set out in [name of document]

Table 2. Staff entitled by ******** NHS trust to act as *practitioners* for justification of exposure of patients to ionising radiation as part of the planning or delivery of radiotherapy treatment**

Name	External beam radiotherapy prescription		Brachytherapy prescription		Pretreatment simulation	Pretreatment planning CT scans	KV verification Images	MV verification images	Re-simulation
	Radical	Palliative	Radical	Palliative					

It is the responsibility of the clinical lead in radiotherapy to assess whether an individual has received adequate training and is competent to act as a *practitioner* before they will be entitled to justify a defined scope of exposures.

It is the responsibility of the clinical lead, head of radiotherapy physics and the radiotherapy services manager to make sure the training records for the staff they line manage are kept up to date.

The responsibilities of the *practitioner* and the procedures for justifying and authorising exposures are set out in [name of document]

Appendix 2. Training matrices

Table 1. Scope of operations for which suitably trained individuals in each staff group are *entitled* to act as *operator*

This table is an example of a matrix of potential entitlement that could be adapted as required. The ticks in particular boxes are presented as an illustration and should not be regarded as definitive.

Operation	Clinical Oncologist	Physicist	Therapy Radiographer	Assistant Therapy Practitioner	Diagnostic Radiographer	MTO	Nurse	Other HCP
Patient identification	✓	✓	✓	✓	✓	✓	✓	✓
Imaging for localisation			✓	✓	✓			
Generation of treatment machine data		✓						
Generation of patient data required for treatment	✓	✓	✓	✓		✓		
Fabrication of treatment aids		✓	✓	✓	✓	✓	✓	✓
Planning of dose distribution	✓	✓	✓					
Prescription	✓							

Table 2. Examples of processes and associated definitions of *operators*

Process element	Context	Responsible operator	Comment
Treatment plan production	Person working alone	Person producing the treatment plan	This person must be an *entitled operator*
	Entitled operator seeking formal advice	Person producing the plan	The person giving the advice is responsible for the advice given but the *operator* may either accept the advice or seek further guidance
	Entitled operator who finds the need of supervision	Supervisor	Eg, when a more complicated plan is being done than has been envisaged by the authorisation system
	More than one *entitled operator* carrying out a plan	Each *operator* involved	Eg, a special case plan involving more than one individual where each is acting as an independent *operator*
	Person who has received training but has not been *entitled* to act as *operator* and must therefore be supervised	Supervisor	The person carrying out the plan is fully trained to carry out that process to the satisfaction of the supervisor but is not entitled to be an *operator*. The supervisor could be indirect
	Supervised untrained person	Supervisor	The supervisor must be physically present to oversee the process
Treatment plan check	*Entitled operator* or *operators* carrying out parts of the checking process	Person or persons carrying out the check indicated by initials against each part of the check	Checks may not be carried out by unauthorised *operators* but may require more than one *operator* to complete it
	Person in training	Supervisor	The supervisor must independently check the plan not relying on the first check
Treatment machine constancy check	Unsupervised *entitled operator*	Person carrying out the check	This person is a fully trained *operator*
	Supervised *entitled operator* working beyond their competence	Supervisor	For example when the first check was not within range
	Supervised trained person but not an *entitled operator*	Supervisor	The person carrying out the check is fully trained to carry out that process to the satisfaction of the supervisor but is not qualified to be an *operator*
	Supervised untrained person	Supervisor	The supervisor must be physically present to oversee the process
Handover of treatment machine following run-up	Trained *operator*	Person handing over the machine	No unauthorised *operator* may hand over a treatment machine for clinical use
Maintenance of equipment	*Entitled operator* working alone or with an unauthorised person	*Entitled operator* maintaining the equipment	Authorisation depends on the entries in their training record
	Supervised *entitled operator* working beyond their competence	Supervisor	
	Supervised untrained person	Supervisor	The supervisor must be physically present to oversee the maintenance
Handover of treatment machine following adjustment of parameters likely to affect treatment	*Entitled operator*	Person handing over the machine	If there is any possibility that there may be a problem with the radiation beam or the dosimetry equipment or if anything has been done to the machine which may affect them the machine may not be handed over for clinical use except by a physicist *operator*

Appendix 3. A checklist for a proactive inspection to assess IR(ME)R compliance

The following list of questions may be helpful in reviewing a department's compliance with IR(ME)R. It is presumed that all staff have familiarised themselves with the requirements of IR(ME)R so that when, for example, an exposure is *justified* the issues laid down in ***Regulation 6*** are considered. For completeness, some issues relating only to diagnostic radiology are included, but these are specifically identified.

1. Are there written procedures ***(Regulation 4(1))*** covering at least the following ***(Schedule 1 and Regulation 8)***?
   - Patient identification, including unusual situations and ensuring that open questions are used
   - *Entitlement* to act as *referrer, practitioner and operator*
   - *Medico-legal exposures* (diagnostic only)
   - Establishment of pregnancy (or breastfeeding) status, including who is responsible and how this is recorded
   - Quality assurance programmes ***(Regulation 4(3))***, including audit to ensure they are followed
   - *Assessment of patient dose and administered activity*
   - *Diagnostic reference levels* (diagnostic radiology only)
   - Instructions to patients who have been administered radionuclides
   - Carrying out and recording a clinical *evaluation* for each exposure including the consideration of patient dose from planning, treatment and concomitant exposures
   - Minimisation of the risk of unintended dose
   - Carrying out of clinical audit comparing against agreed standards
   - What audit or other steps are taken to ensure that the written procedures are complied with?
2. Are there written protocols ***(Regulation 4(2))*** in place for standard practices?
3. Is there a list or roadmap to show all the written procedures, protocols and work instructions in radiotherapy ***(Regulation 4(2))*** that relate to IR(ME)R?
4. Are there referral criteria ***(Regulation 4(3))*** including radiation doses (eg, radiotherapy protocol book) that are available to *referrers*?
5. Are there any research exposures where there is no medical benefit and, if so, have dose constraints ***(Regulation 4(3))*** been set?
6. What procedures are in place to ensure that referrals for radiation exposure ***(Regulation 5(5))*** are carried out in an appropriate way and that adequate data are provided to *practitioners* to allow them to *justify* the exposure?
7. Are *practitioners* and *operators* aware of their duties ***(Regulation 5)*** under IR(ME)R? What evidence is there of this?
8. What procedures are in place to ensure that all exposures have been *justified* and *authorised* ***(Regulation 6(1))*** by an *entitled practitioner* and that there is written evidence of this *justification*?
9. Are *practitioners* aware of the doses associated with prescribed concomitant exposures so that they can appropriately justify them ***(Regulation 6(2))***?
10. If concomitant exposures are *authorised* as part of the therapeutic course of radiation is there clarity about what exposures will be made? If the number *authorised* is reached, are there processes in place to ensure that any further exposures are *justified* by a *practitioner*?
11. Are procedures in place to consider and minimise the dose to the fetus when treatment of a pregnant women is essential ***(Regulation 6(3ci))***?
12. Are systems in place to ensure that treatment planning exposures ***(Regulation 6(1))*** have been justified prior to the exposure?
13. Do procedures for emergency situations take into account the requirement for *justification* and *authorisation* of exposures ***(Regulation 6(1))*** by an *entitled practitioner*?
14. Are there situations in which an *operator* is permitted to *authorise* an exposure ***(Regulation 6(5))*** and, if so, are there procedures to regulate this laid down by a *practitioner*?

15. Is it clearly laid down who is the *operator* ***(Regulation 5(4))*** in all situations and is a record made of which *operator* carried out each practical aspect of a patient's treatment? (For example, when a patient is treated, an *operator* must identify the patient ***(Schedule 1b)***, establish that the exposure has been *justified* and *authorised* ***(Regulation 6(1a, b))***, that pregnancy status has been established if relevant ***(Regulation 6(1e))***, set up and initiate the exposure. *Operator* responsibilities for all these issues must be clearly defined.)

16. Are there provisions to ensure that a *medical physics expert* ***(Regulation 9)*** is *closely involved in every radiotherapeutic practice*, available for radionuclide therapy and available for consultation in diagnostic radiology?

17. Do training or other records make clear who is *entitled* to act as a *medical physics expert*?

18. Is there a list of radiation equipment ***(Regulation 10(2))*** including the name of the manufacturer, the model and serial number and the year of manufacture and installation?

19. Is there equipment ***(Regulation 10(3))*** that is never used? Is it still required?

20. Are up-to-date training records ***(Regulations 4(4b), 11(4))*** maintained for all staff groups acting as *practitioners* or *operators* including basic professional training, CPD, and training related to the particular equipment and techniques in use, especially when new techniques are introduced? Does the record include the nature of the training and the dates on which the training was received?

21. Does training include all the relevant items listed in ***Schedule 2***?

22. Where temporary staff are employed by an agency ***(Regulation 11(5))***, have enquiries been made to ensure that the agency holds appropriate records of training?

23. Is there a system in place for the investigation and reporting, if necessary, of radiation overexposures ***(Regulation 4(5))***?

24. For diagnostic radiology, what action ***(Regulation 4(6))*** is taken if *diagnostic reference levels* are exceeded? (Note that this is only relevant if radiotherapy equipment is being used in the context of diagnostic radiology; eg, when a scanner is shared to cover breakdowns.)

Appendix 4. *Appropriate authorities* for notification of incidents

England

http://www.healthcarecommission.org.uk/serviceproviderinformation/irmer2000.cfm

Each notification is given a unique IR(ME)R reference number as it is automatically logged on to the Healthcare Commission system.

The IR(ME)R reference number assigned by HCC should be quoted in all correspondence.

IRMER@healthcarecommission.org.uk

Wales

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Department of Public Health and Health Professionals
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Glossary

In the IR(ME)R regulations certain terms are specifically defined. Their meaning differs from that of the term in common usage and must be understood in this context. Examples include the use of the words '*referrer*', and '*practitioner*'.

Authorisation	*Authorisation* is the verification that the process of *justification* has taken place and is usually demonstrated by the signature of the *practitioner*. In addition, an *operator* can authorise exposures within guidelines set by the *practitioner* (see Section 2.14)
Employer	In IR(ME)R the *employer* is defined as *any natural or legal person who, in the course of the trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures of practical aspects, at a given radiological installation*. The *employer* is a duty holder under IR(ME)R and is responsible for providing a framework within which professionals undertake their functions (see Section 1.1)
Evaluation	Clinical *evaluation* is required in order to ensure that exposures have been *optimised* and are appropriate (see Section 2.16)
Justification	*Justification* is the process of weighing up the potential benefit of an exposure against the potential detriment for that individual. It must include considering the possibility of using techniques which do not use ionising radiation (see Section 2.9)
Operator	An *operator* is defined in IR(ME)R as *any person who is entitled, in accordance with the employer's procedures, to carry out technical aspects*. They do not have to be a *registered healthcare professional*. The *employer* should specify the scope of practice and the task for which an individual can operate as an *operator. No practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained*. ***(Regulation 11)*** (see Section 2.12)
Optimisation	*Optimisation* is the process by which individual doses are kept as a low as reasonably achievable. This includes individualised planning and the use of appropriate equipment with a quality assurance programme (see Section 2.15)
Policy/procedure/protocol:	**Policy** – A high level statement governing the conduct of activities in the organisation. Policies set constraints with little or no expectation of variation **Procedure** – A more detailed description of the control mechanisms for a process indicating detailed management arrangements and responsibilities **Protocol** – Guidance on the detail of a treatment process based on a consensus of opinion.
Practitioner	A *practitioner* is a *registered healthcare professional* who is *entitled* by the *employer* to *justify* and *authorise* the exposure of a patient to ionising radiation as a part of the whole treatment process (see Section 2.8)

Working Party Membership

David Bloomfield	The Royal College of Radiologists (Chair)
Sian Davies	The Royal College of Radiologists
Steve Ebdon-Jackson	Health Protection Agency
Michael Graveling	The Society and College of Radiographers
Philip Mayles	Institute of Physics and Engineering in Medicine
Maria Murray	The Society and College of Radiographers
Carol Nix	Health Protection Agency
Michael Williams	The Royal College of Radiologists

Approved by the Board of the Faculty of Clinical Oncology of The Royal College of Radiologists: March 2008

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