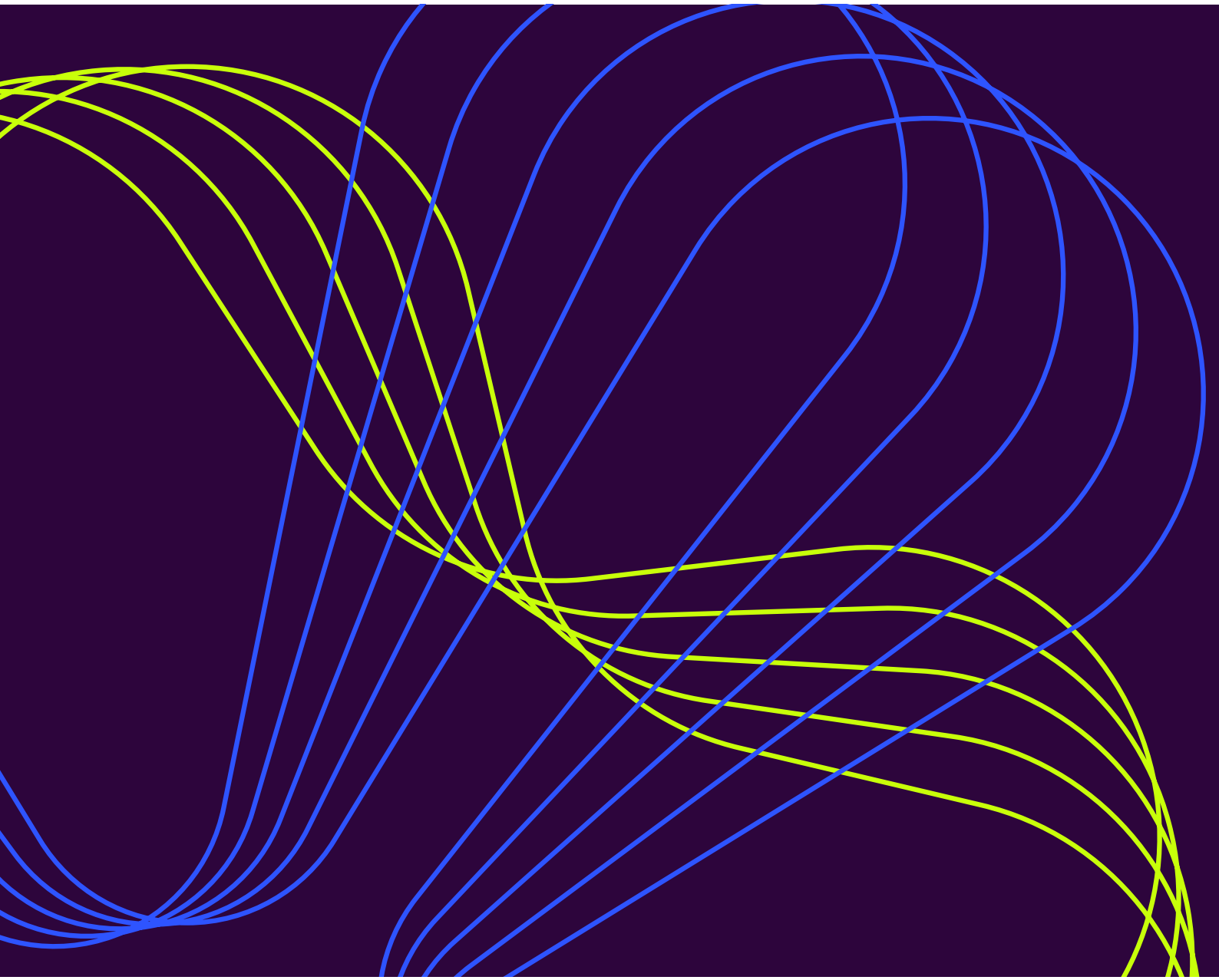
IR(ME)R:
Implications for clinical practice in radiotherapy, second edition
Guidance from the Radiotherapy Board

Produced in association with UK Health Security Agency

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The Royal College of Radiologists



SoR THE SOCIETY OF RADIOGRAPHERS

IPEM Institute of Physics and Engineering in Medicine

UK Health Security Agency

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Foreword

The Ionising Radiation (Medical Exposure) Regulations 2017 and Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 aim to protect the patient by providing a framework for the safe use of ionising radiation in medical and non-medical imaging using medical radiological equipment. The regulations specify the roles and responsibilities of four duty holders: the employer, referrer, practitioner and operator. The principles of justification, optimisation and adequate training of practitioners and operators are fundamental to the regulations.

On 1 October 2024, the Ionising Radiation (Medical Exposure) Amendment Regulations 2024 came into force in England, Scotland and Wales. The regulations in Northern Ireland have not been amended.

This second edition of guidance seeks to explain how the requirements of the amended regulations should be interpreted and used in clinical practice. Updates have been made across the document to reflect changes to service provision and developments in technology. Clinical scenarios have been included to enable practical interpretation of the regulations. In addition, professional guidance for the development of training records for clinical oncologists has been incorporated into this guidance.

This guidance has been produced by a working party, which included representatives from:

- Institute of Physics and Engineering in Medicine
- Medical Exposures Group, UK Health Security Agency
- The Royal College of Radiologists
- The Society and College of Radiographers

We hope this document will support the radiotherapy community, including molecular radiotherapy and brachytherapy, to effectively implement IR(ME)R in their clinical practice.

01 Introduction

This guidance document is intended to provide a practical approach to implementing the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024[1] for all staff groups delivering a range of radiotherapy services including molecular radiotherapy (MRT). It replaces the 2020 publication: *Ionising Radiation (Medical Exposure) Regulations: Implications for Clinical Practice in Radiotherapy.*[2]

Amendments to IR(ME)R 2017 (Great Britain) came into effect in 2024, applicable within England, Wales and Scotland.[1] At time of publication the amendments have not been adopted by Northern Ireland. However, these are currently under review.[3] The amendments support good practice and learning from the clinical implementation and enforcement of the regulations. Therefore, the following guidance reflects the IR(ME)R amendments 2024 and any reference to IR(ME)R can be taken to refer to these regulations, unless specifically stated. Within the UK, responsibility for healthcare is devolved and different approaches may be taken in each of the four nations.[1,3]

This document refers to radiotherapy in general, but where requirements or practice differ between external beam radiotherapy, brachytherapy or MRT this is stated. Typical scenarios and examples have been included to provide practical advice on aspects of the regulations. These are taken from information provided to the working party by several departments and are not intended to be prescriptive. This document should be read in conjunction with IR(ME)R and other published guidance.[4] A glossary of terminology used in this guidance is included in Appendix 1.

The following guidance reflects the requirements of the 2024 amendments to IR(ME)R, including:

- Introduction of co-operation between employers when there are multiple employers involved in the delivery of an exposure to an individual (see Chapter 2).
- Development of employer's responsibilities to ensure appropriate action is taken regarding clinical audit (see Chapter 3) and accidental or unintended exposures (see Chapter 19).
- Introduction of dose reference levels for localisation or verification exposures (see Chapter 9).
- Development of employer's responsibilities in regard to the management of equipment including software (see Chapter 18).
- Update to definitions [Regulation 2] to minimise confusion and resolve ambiguity in interpretation.
- Update to adequate training [Schedule 3] to improve formatting and layout (see Chapter 4).
- Development of Schedule 2 to include employer's procedures for the carrying out of clinical audit and appropriate action taken and procedures for making, amending and cancelling a referral (Chapter 3 and 6).

In addition, professional guidance for the development of training records for clinical oncologists has been included (see Chapter 4 and Appendix 5).

01
Introduction

The regulations

IR(ME)R implements the medical exposure provisions from the European Council Basic Safety Standards Directive 2013/59/Euratom (BSSD).[5] The BSSD takes into account the recommendations from the International Commission on Radiological Protection (ICRP) publication 103.[6]

IR(ME)R places obligations on specific duty holders and provides a framework intended to protect individuals from the hazards associated with medical exposures involving ionising radiation. The responsibility for compliance with IR(ME)R lies with the employer and each of the entitled duty holders. The roles and responsibilities of all duty holders are explained in detail in Chapter 2.

IR(ME)R applies to the medical exposures and specific types of non-medical exposures listed in Table 1.1 [Regulation 3].

Table 1.1: Types of exposures addressed within IR(ME)R

	Exposure	Radiotherapy examples
Medical exposures	Patients, as part of their medical diagnosis or treatment	All radiotherapy treatments, using either external beam, sealed radioactive sources (brachytherapy) or unsealed sources (MRT) All associated (concomitant) planning or verification imaging, using X-rays or unsealed sources
	Individuals as part of health screening programmes	Not applicable for radiotherapy
	Individuals participating in research programmes	Patients taking part in clinical trials
	Carers and comforters	Individuals who provide support and comfort to a patient within a controlled or a supervised area (where access is normally restricted, or systems of work are in place to exclude members of the public) Individuals who provide support and comfort and are not able or willing to follow the usual instructions regarding radiation protection precautions for patients who have been administered radioactive substances
	Asymptomatic individuals	Not applicable for radiotherapy
Non-medical exposures	Individuals undergoing non-medical imaging using medical radiological equipment	Not applicable for radiotherapy

01 Introduction

Exposures within health screening programmes are carried out on asymptomatic individuals who are part of an apparently healthy target group or population who are deemed to be at increased risk from a specific condition or disease (eg the national breast screening programme). Non-medical imaging exposures using medical radiological equipment are defined as exposures that do not give a direct health benefit to the individual exposed.[4] Examples include:

- Health assessment for employment, immigration or insurance purposes
- Identification of concealed objects within the body.

It is expected that health screening and non-medical imaging will not be undertaken as part of radiotherapy procedures. A statement that these types of exposures are not undertaken in the local department should be included in the departmental IR(ME)R employer's procedures or similar.

Further guidance on exposures as part of health screening programmes is available.[7]

02 Duty holder roles and responsibilities

Responsibility

The responsibility for compliance with IR(ME)R lies with the employer, each of the entitled duty holders and any other employees involved. The roles and responsibilities of all duty holders are explained in this chapter. Each duty holder has personal and professional responsibility for ensuring the regulations are complied with.

An individual duty holder's legal responsibility is to act in the way the employer has set out in the employer's 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 a medical exposure to a patient.
- Be able to challenge the actions and decisions of others, as appropriate, if their performance is likely to result in ineffective or unsafe delivery of an exposure. It is the valued role of any healthcare professional to look beyond their traditionally defined boundaries to improve care for patients.

Professionally it is the responsibility of healthcare staff to challenge the decisions of others if they feel patient safety is at risk and to bring this to the attention of a senior colleague such as the service manager, head of physics or clinical lead. Doing so can avert serious adverse events. It is a professional responsibility, rather than a duty under IR(ME)R, to be alert to the possibility of an error from any source and ensure that nonconformances are raised within the quality management system (QMS).

The medical care of a patient is led by staff of consultant status. The consultant has a professional and general medico-legal responsibility for the medical management of the patient. They are responsible under IR(ME)R for each task they undertake (eg referral), but they cannot be held responsible for those tasks carried out by other duty holders (eg treatment planning).

A signature indicates the duty holder is taking responsibility for that specific task. 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. Electronic signatures have been adopted in many areas of radiological practice to replace handwritten signatures.[8] Electronic signatures are only as secure as the business processes and technology used to create them. In practice these are included in systems such as the oncology management system (OMS), treatment planning system (TPS), electronic referral systems, electronic patient record (EPR), radiology information system (RIS) and picture archiving and communication systems (PACS). Users should have personal passwords as signatories to access these systems, and system entries should be timestamped. Users should be made aware of local procedures governing the use of IT and the General Data Protection Regulation (GDPR).[9] Further detail on electronic signatures can be found in Chapter 6.

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Duty holder roles and responsibilities

An individual may be entitled to act as more than one duty holder within a defined scope of practice, for example referrer, practitioner and operator for breast radiotherapy. Such individuals are responsible as each of these duty holders [Regulation 2(2)]. Responsibility cannot be delegated; 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 work must be overseen, reviewed or checked and must be approved by the person responsible. Further detail on supervision can be found in Chapter 4.

Inappropriate delegation has been identified as a known cause of patient safety events and should be avoided. For example, when initiating an exposure, it is best practice to identify the patient yourself rather than delegate this task.

Regulation 19 provides a defence of due diligence. If a duty holder has, so far as reasonably practicable, taken all steps to comply with the regulations, they may be able to offer a defence of due diligence. Practical ways of demonstrating that all reasonable steps have been taken include documentation of:

- Identification checks
- Pregnancy and breastfeeding checks
- Discussions with individuals exposed
- Quality assurance (QA) records
- Clear, accurate and up-to-date employer's procedures.

02

Duty holder roles and responsibilities

Employer

In IR(ME)R the definition of the employer 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 provided through written procedures, written protocols and QA programmes. The employer has a statutory duty to make sure that these are in place [Regulation 6]. The duties of the employer are set out in Table 2.1.

Table 2.1: Requirements of the employer

Regulation	Requirement	Things to consider
Regulation 5(1)(a)	Licensing for the administration of radioactive substances	• Ensure appropriate, valid employer licence is in place for scope of service at each site (see Chapter 20)
Regulation 6	General procedures, protocols and QA	• Establish written employer's procedures required in Schedule 2 (see Appendix 3) • Ensure written procedures are complied with by the practitioner, operator and referrer • Establish referral guidelines • Ensure referrals are made in accordance with employer's procedures and guidelines (see Chapters 4 and 6) • Have a QA programme in place for documentation (see Chapter 3) • Establish written protocols for standard radiological practices • Develop and review dose reference levels (DoRLs) for typical localisation and verification imaging exposures (see Chapter 9) • Ensure practitioners and operators are adequately trained and engage in continuing professional development (CPD) and education after qualification (see Chapter 4) • Establish dose constraints for research exposures (see Chapter 21) and for carers and comforters (see Chapter 16)
Regulation 6A	Co-operation between employers	• Where required, co-operate with employers to ensure each employer has access to information on the exposure (or potential exposure) and is enabled to comply with the requirements of IR(ME)R (see Chapter 2)
Regulation 7	Clinical audit	• Ensure the employer's procedure details how and when clinical audit is carried out and appropriate action is taken, with dissemination of results to appropriate stakeholders (see Chapter 3)

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Duty holder roles and responsibilities

Regulation 8	Accidental or unintended exposures (AUE)	• Ensure the employer's procedure details how the referrer, practitioner and individual exposed (or their representative) is informed of clinically significant accidental or unintended exposures (CSAUE) and the outcome of analysis of the exposure • Report, investigate and analyse actual and potential AUE, ensuring appropriate action is taken (see Chapter 19) • Establish a study of the risk of AUE
Regulation 12(9)	Clinical evaluation	• Ensure a clinical evaluation is recorded for every exposure except for carers and comforters (see Chapter 11)
Regulation 13	Population doses	• Ensure dose estimates from medical exposures are collected
Regulation 14(1)	Expert advice	• Appoint a suitable medical physics expert (MPE) (see Chapter 17)
Regulations 15(1), 15(3), 15(6)	Equipment	• Maintain an equipment inventory • Implement and maintain an equipment QA programme • Implement measures to address poorly performing equipment (see Chapter 18)
Regulations 17(4), 17(5)	Training records	• Keep appropriate training records and ensure they are available for inspection (see Chapter 4) • Share training records between employers (see Chapter 4)
Schedule 2	Written employer's procedures	• Have in place the minimum requirement of 16 employer's procedures • Review and update periodically (see Chapter 3)

Under IR(ME)R, the employer is legally responsible, when establishing practices for the safe delivery of radiotherapy, for ensuring that robust written procedures exist including those listed in Schedule 2 [Regulation 6(1)]. It is essential that procedures are regularly reviewed and updated. Such procedures must be documented and define the responsibilities of every duty holder involved in the process, including the employer.

The organisation should designate an accountable representative to ensure the employer's duties are fulfilled. The individual undertaking this role must hold a senior position within the organisation, usually at board level or as part of the executive team. In NHS services, this individual is generally the chief executive unless an alternative individual has been formally designated. The individual's role should relate to all those professional groups that provide elements of the service and should ideally incorporate all other services using ionising radiation.

The detailed implementation of IR(ME)R may be delegated to an appropriately trained and experienced professional, such as a clinical lead for radiotherapy or medical director. However, the legal responsibility for safe IR(ME)R practice and procedures cannot be delegated and always remains with the employer. The employer must be aware of their responsibilities under IR(ME)R and ensure those tasks they have delegated are appropriately discharged.

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Duty holder roles and responsibilities

Employers may establish management structures or committees of responsible staff, such as a radiation protection committee (RPC) or medical exposures committee (MEC), to formulate appropriate policies, procedures and protocols, audit and monitor the level of compliance with IR(ME)R, identify remedial action to improve compliance, drive continual improvement via clinical audit and the systematic analysis of actual and potential AUE, and keep the employer informed of specific issues that require attention. These also provide a framework for formal adoption of changes to practice and documentation (management of equipment procurement and replacement programmes, introduction of new techniques, entitlement practices, and so on). The RPC or MEC should feed up through the governance framework for providing assurance to the employer of organisational compliance.

Co-operation between employers

Where two or more employers work together to refer, justify, carry out or clinically evaluate an individual's exposure, they must co-operate with each other to ensure the requirements of IR(ME)R are being met [Regulation 6A]. Co-operation between employers enables the co-ordination of services to minimise risks and ensure patient safety.

Co-operation between employers is required in the following clinical scenario examples:

- Outsourcing of services to another employer, for example specialist services such as brachytherapy.
- Insourcing of services, for example as part of national or regional initiatives where external staff utilise local equipment and facilities to provide a service.
- Utilisation of non-substantive staff, for example third-party providers in the provision of medical physics support.

Arrangements detailing the relevant IR(ME)R governance structure across the entire patient pathway should be explicitly recorded in agreed documentation, for example a service-level agreement or contract. Agreed documentation must outline the relevant IR(ME)R governance structure and chain of accountability. Duty holders should be aware of and understand the arrangements that have been put in place by the employers.

The employers need to agree and document how each of their IR(ME)R responsibilities are defined and allocated across the exposure pathway. This should include training, competency and entitlement of the duty holders involved in the pathway. Bespoke agreements will be required and should be tailored to the services that are shared between the employers.

Table 2.2 includes considerations for the IR(ME)R governance structure as well as each part of the exposure pathway.

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Duty holder roles and responsibilities

Table 2.2: Considerations for co-operation between employers

IR(ME)R governance structure

- Clear outline of IR(ME)R roles and responsibilities at each part of the exposure pathway
- Clear understanding of which employer's procedure, policies and written protocols staff are working to
- Adequate training and entitlement of staff
- Management and QA of equipment including handover arrangements where necessary
- Access to relevant clinical documentation and patient records
- Management of patient safety events, including responsibility for reporting, responding, analysing, taking appropriate action and communicating outcomes
- Processes in place for clinical and IR(ME)R audit, including taking appropriate action and communicating results
- Licence considerations for the administration of radioactive substances at site

Referral	Justification	Practical aspects
• Access to employer's procedures and referral guidelines	• Access to employer's procedures and relevant protocols	• Access to employer's procedures and relevant protocols
• Individual or group entitlement	• Access to training records	• Access to training records
• Compliance with written procedures	• Individual or group entitlement	• Individual or group entitlement
• Consideration of local protocol	• Compliance with written procedures	• Compliance with written procedures
	• Licence considerations for the administration of radioactive substances	• Access to patient information pertaining to the exposure
	• Access to patient information pertaining to the exposure	• Access to information required for optimisation
	• Access to information required for optimisation	• Management of equipment

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Duty holder roles and responsibilities

Referrer

The referrer must be a registered healthcare professional as defined in IR(ME)R.[1] In Northern Ireland, this also includes medical practitioners registered with the Medical Council of Ireland.

Referrers are entitled, by the employer, to request that a patient is exposed to ionising radiation as part of a therapeutic process. Referrals are made taking into account the referral guidelines provided by the employer and knowledge of the benefit and risk associated with the intended exposure. Some departments may accept referrals from outside their own organisation for specialist services. In all situations, the employer's procedures must state how referrals are made, amended and cancelled. They should also include from whom referrals are accepted and how the referrer will be provided with the specified referral guidelines. Referrer awareness training is discussed in Chapters 4 and 6. Referrers must ensure the patient information is as accurate as possible. The roles and responsibilities of the referrer are set out in Table 2.3.

Table 2.3: Requirements of the referrer

Regulation	Requirement	Things to consider
Regulation 6(5)(a)	Referral guidelines are made available	• Access to established guidelines that can be used to make a referral • When and how to seek advice on non-standard referrals
Regulation 10(1)	Employer's procedures	• Read and comply with employer's procedures
Regulation 10(5)	Sufficient medical data are supplied	• Provide enough information to identify the individual (see Chapter 12) • Provide information on relevant clinical history to enable justification by practitioner (see Chapter 6) • Where relevant provide information on pregnancy or breastfeeding (see Chapter 13)
Schedule 2(b)	Individual entitlement	• Understand specified scope of practice (see Chapter 5) • Adhere to limited referral rights when they are applied • In radiotherapy, the scope of practice may be limited to referral for planning, treatment or verification, or be any combination of the three
Schedule 2(p)	Management of referrals	• Making, amending and cancelling referrals • May also include training for referrers (if appropriate), description of the referral process, communication requirements and where to access referral guidelines or further guidance

See Chapters 4, 5 and 6 for further information on the referral process, referral guidelines, referrer training, entitlement and scope of practice.

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Duty holder roles and responsibilities

Practitioner

The IR(ME)R practitioner's primary role is the justification of exposures. The practitioner must be a registered healthcare professional as defined in IR(ME)R and comply with the employer's procedures [Regulation 10(1)]. Practitioners who wish to justify exposures involving the administration of radioactive substances must hold a valid practitioner licence [Regulation 5(1)(b)]. Further information on licensing is available in Chapter 20.

The practitioner is entitled by the employer to justify and authorise the exposure of a patient to ionising radiation. The process of justification and authorisation is described in more detail in Chapter 7. To perform this action, the referral is assessed against the clinical data supplied by the referrer. The practitioner must have had adequate training and be competent to consider the potential benefits of the exposure against the potential detriment for that individual.

Before justifying an exposure, the practitioner should review the results of any relevant previous investigations and consider the possibility of alternative modalities that do not involve exposure to ionising radiation. The roles and responsibilities of the practitioner are set out in Table 2.4.

Table 2.4: Requirements of the practitioner

Regulation	Requirement	Things to consider
Regulation 5(1)(b)	Licence for administration of radioactive substances	• Hold a valid practitioner licence (see Chapter 20) • Understand what is specified in the licence • Adhere to the terms
Regulation 10(1)	Employer's procedures	• Read and comply with employer's procedures
Regulations 10(2), 11(1), 11(2), 11(3) and 11(4)	Justification of the exposure	• Consider the benefits and risks of the exposure • Evaluate the information provided (see Chapter 7) • Choose a modality that best addresses the clinical problem • Request further information if required • Take into account guidelines issued by professional or relevant bodies • Authorise exposures that are justified • Consider justification of exposures to carers and comforters (see Chapter 7) • Consider the urgency of the exposure • Document relevant information • Consider justification of exposures to carers and comforters

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Regulation 10(6)	Co-operate with other staff	• Share relevant information • Participate in multidisciplinary team meetings (MDTMs) • Provide multiprofessional support and advice
Regulation 11(5)	Task of authorisation	• Issue authorisation guidelines to be used by operators where required (see Chapter 7) • Retain responsibility for justification of exposures authorised under guidelines
Regulation 12(1)	Optimisation	• Ensure concomitant exposures are kept as low as reasonably practicable (see Chapter 8)
Regulation 12(2)	Optimisation	• Ensure therapeutic exposures are individually planned and appropriately verified
Regulation 12(8)	Pay particular attention	Optimisation of: • Paediatric exposures (see Chapter 15) • Therapeutic exposures • Pregnancy status (see Chapter 13) • Breastfeeding status (see Chapter 13)
Regulation 17(1)	Training	• Adequate training as defined in Schedule 3 (see Chapter 4) • Training and competency on local equipment and techniques • Training on new techniques and technology
Schedule 2(b)	Individual entitlement	• Understand specified scope of practice (see Chapter 5) • Ensure entitlement is reviewed and updated when new skills are added • Remove entitlement of specific tasks when no longer competent or required

The employer should specify the scope of practice for which an individual can act as a practitioner and be able to demonstrate that they are adequately trained to perform these tasks. The scope of practice may be limited, for example, to justification of planning, verification or treatment exposures or any combination of each type of exposure in radiotherapy. It is important that this is defined in written procedures.

In radiotherapy, the referrer and practitioner for a course of treatment may be the same person entitled to undertake both functions. 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 local procedures.

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Duty holder roles and responsibilities

Operator

The operator does not have to be a registered healthcare professional. The operator is any person who is trained and entitled, in accordance with the employer's procedures, to carry out practical aspects relating to the exposure [Regulations 10(3) and 17(1)]. The operator is individually responsible for all practical aspects of a procedure that they undertake.

Some examples of practical aspects include:

- Patient identification
- Checking pregnancy or breastfeeding status
- Outlining or review of volumes on the TPS
- Preparing or checking the treatment plan
- Operating the imaging equipment
- Initiating the treatment exposure
- Dispensing/assay of radiopharmaceuticals
- Administration of a radiopharmaceutical
- Image manipulation and archive
- QA of radiation equipment
- Clinical evaluation
- Clinical patient review.

Operator functions may be carried out by clinicians, radiographers, MPEs or other trained medical physics staff including clinical scientists and clinical technologists. Authorisation may be carried out by either a practitioner or an operator [Regulation 11(1)(c)]. Where the practitioner is not available and the authorisation process is carried out by an operator they must follow authorisation guidelines issued by the practitioner [Regulation 11(5)].

Automation and artificial intelligence (AI) technologies must only be used in an assistive capacity for the practical aspects of an exposure, as an individual must be involved [Regulation 10(3)]. The process for any use of assistive software including AI should be clearly described in written procedures including sufficient training, QA and the establishment of performance monitoring.[10,11]

Maintenance of equipment does not fall within the definition of 'practical aspects relating to an exposure'. Third-party service engineers would not normally be entitled as operators. In most circumstances, third-party engineers, whether providing initial installation or servicing, ongoing maintenance or repair, are responsible for presenting a machine in a safe condition and working to the manufacturer's specifications. They are not usually responsible for the equipment being in a state fit for clinical use; further measurements and verification are needed before the equipment can be used clinically. Usually, an MPE will take responsibility for this process (see Chapter 18).

In-house engineers whose sole responsibility is maintenance and repair of equipment will similarly not normally need to be entitled as operators. However, if their scope of practice extends beyond this, into QA of equipment for example, then they will need to be entitled for this aspect of their role. The roles and responsibilities of the operator are set out in Table 2.5.

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Table 2.5: Requirements of the operator

Regulation	Requirement	Things to consider
Regulation 10(1)	Employer's procedures	• Read and comply with employer's procedures
Regulations 10(3), 10(4)	Practical aspects	• Training required to carry out any practical aspects and/or authorisation of exposures to guidelines issued by practitioner (see Chapter 4) • Allocation of responsibility to appropriate specialist staff
Regulation 10(6)	Co-operate with other staff	• Share relevant information • Participate in MDTMs • Provide multiprofessional support and advice
Regulation 12(1)	Optimisation	• Ensure concomitant exposures are kept as low as reasonably practicable (see Chapter 8)
Regulation 12(3)	Selection of equipment and methods	• Choose the appropriate equipment and approach for the individual (see Chapter 8) • Assess and evaluate dose during and after the procedure
Regulation 12(8)	Pay particular attention	• Paediatric exposures (see Chapter 15) • Therapeutic exposures • Pregnancy status (see Chapter 13) • Breastfeeding status (see Chapter 13)
Regulation 17(1)	Training	• Adequate training to carry out any practical aspect of an exposure (see Chapter 4) • Training and competency on local equipment and techniques • Training on new techniques and technology
Regulation 2(b)	Individual entitlement	• Understanding of specified scope of practice (see Chapter 5) • Ensure entitlement is reviewed and updated when new skills are added • Remove entitlement of specific tasks when no longer competent or required

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 that they are adequately trained to perform these tasks. It is important that this is defined in written procedures.

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Duty holder roles and responsibilities

Scenario 1

Outlining and review of the target volume is an important practical aspect of the treatment exposure. Target volume definition requires an assessment of clinical information and imaging to identify the location of the tumour (or tumour bed in the case of adjuvant treatment) and provide an understanding of the possible routes of microscopic spread and an appreciation of potential positional errors. The uncertainties involved in this complex decision-making process mean that there is the potential for variability, bias and error. Professional guidance is available to inform practice and define minimum standards for volume definition and peer review of contours. [12]

Prospective peer review of the target volume involves the formal review of the delineated contours by another trained and entitled operator, for example a site-specific clinical oncologist. Peer-review processes may be implemented locally or between departments via trust or cancer alliances. Where individuals review and change the delineation of target volumes prior to treatment planning or delivery, the individual must be appropriately trained and entitled as an operator. Where prospective peer review occurs between departments due consideration must be given to co-operation between employers.

A medical exposure using ionising radiation must be performed by an operator who has been trained, deemed competent and entitled to perform these procedures by the employer. The operator is responsible for checking patient information as provided to ensure the correct individual is being exposed. They are also responsible for patient positioning and ensuring the appropriate exposure is used, for example the correct plan in adaptive treatments. Further information on training requirements is included in Chapter 4.

Non-statutory-registered operators

Some staff groups are not registered with a formal regulatory body such as the Health and Care Professions Council (HCPC), for example assistant practitioners (APs), clinical technologists or healthcare science practitioners. It is important to note that the term 'practitioner' in this context is different from the term as defined by IR(ME)R.

While not a requirement of IR(ME)R, APs may be accredited by the College of Radiographers (CoR) and entered onto the CoR public voluntary register.[13] APs who are not on the voluntary register but have completed an in-house training programme may be assessed as competent and entitled as operators to carry out specific practical aspects of an exposure.

Once an AP has been trained and deemed competent, they can be entitled as an operator with a specific scope of practice. However, a radiographer should always be available to provide support and advice on radiographic practice.

Another example of non-statutory-registered operators is healthcare science practitioners, who are graduates with a healthcare science degree and who have completed a practitioner training programme, or individuals who have demonstrated equivalence with that training programme (eg clinical technologists) through accreditation by the Academy for Healthcare Science (AHCS) or the Institute of Physics and Engineering in Medicine (IPEM). Healthcare science practitioners are eligible to join an assured Register of Healthcare Science Practitioners through the AHCS or the assured Register of Clinical Technologists through IPEM.[14,15] The assured registers are accredited by the Professional Standards Authority.[16]

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Duty holder roles and responsibilities

Registration of healthcare science practitioners and clinical technologists is good practice, especially for those who may work independently. Staff may be eligible to join the register after a period of accredited training or by submission of a portfolio of evidence that demonstrates equivalence. Those who are not on a register should be trained and assessed locally as described above.

Before entitling a non-statutory-registered individual 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 3 of the regulations. The scope of such entitlement must be clearly documented, as it is for all staff groups. When these individuals are acting as entitled IR(ME)R operators, they are each legally responsible for their actions.

03 Procedures, document control and audit

Procedures and protocols

Regulation 6(1) requires the employer to have in place written procedures as specified in Schedule 2 as a minimum. Within the radiation safety framework, the employer may choose to have additional employer's procedures to cover the full range of service delivery.

When a type of exposure (see Table 1.1) is not carried out as part of a local service, for example non-medical imaging or research exposures, an employer's procedure is still required. This could include a clear statement such as 'No research exposures are carried out in this trust'.

Employer's procedures must be documented and define the responsibilities of duty holders involved in the process. They should include clear instructions on how and when a process should be carried out and who is responsible. Appendix 3 details things to consider for inclusion within employer's procedures.

The employer must ensure written protocols are in place for every type of standard radiological practice [Regulation 6(4)]. In practice, radiotherapy departments have established site- or disease-specific clinical protocols or clinical management guidelines. It is recommended that, in radiotherapy, these be peer reviewed and evidence based, with the use of a standard template and subject to the QA programme. Appendix 4 provides a list of example fields for inclusion in the standard protocol template.

It is recommended that specialists in the relevant fields are actively engaged in the development of procedures and protocols.

Quality assurance programmes for documentation

Regulation 6(5)(b) requires that the employer must have in place QA programmes for written procedures and protocols. There is a requirement to have an employer's procedure to ensure the QA programmes for written procedures and written protocols are followed [Schedule 2(d)].

An employer's procedure in respect of QA programmes for radiological equipment is also required. More detail can be found in Chapter 18. QA is defined in the regulations as: 'any planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with generally applicable standards and quality control is a part of quality assurance' [Regulation 2].

It is imperative that proper QA measures are in place to achieve and maintain the required degree of accuracy, to reduce the likelihood of patient safety events and to increase the probability that any adverse events that occur will be recognised and rectified.[17] QA guidelines specific to radiation treatment have been issued by a number of worldwide organisations, including the World Health Organization (WHO),[18] the International Atomic Energy Agency and the ICRP. [19–21]

03

Procedures, document control and audit

The benefits of using a robust QA system include:

- Supporting safer service delivery
- Promoting a consistent approach to service delivery
- Providing some assurance of service quality to the employer
- Ensuring up-to-date documents are accessible
- Driving continual service improvement through review.

To attain these benefits, all routine work should be carried out in accordance with approved documentation, and all non-routine work that may affect treatment outcome should be approved through a system of written 'concessions' as part of a QMS.

QA programmes for written procedures and protocols in radiotherapy are successfully managed through a QMS, which might be defined as a formalised system that documents processes, procedures and responsibilities for achieving objectives. External review and accreditation or certification schemes for QMS are available (eg International Standard ISO 9001) [22] but there is no legal requirement for this in IR(ME)R. However, as early as 1994 the Bleehen Report Quality Assurance in Radiotherapy recommended a QA framework based on ISO, which was echoed in Towards Safer Radiotherapy in 2008.[23,24] This is also a requirement of the NHS England external beam radiotherapy service specification.[25]

A QMS can help compliance with IR(ME)R, but it must be clear which documents are intended to form part of the IR(ME)R procedures. Failure to follow these employer's procedures could be deemed a breach of legislation.

The employer is responsible for implementing IR(ME)R consistently throughout the organisation – not just in radiotherapy. An organisation-wide document may be established to achieve this, for example within a radiation safety policy. Care needs to be taken that local, modality-specific procedures are consistent with any organisation-wide documents. For example, where entitlement of referrers and practitioners differs between external beam radiotherapy and brachytherapy or MRT, this should be specifically stated in the local procedures. Table 3.1 includes matters to consider when establishing a QA programme.

03

Procedures, document control and audit

Table 3.1: Considerations when establishing a QA programme

QA programme	Things to consider
How are written procedures and protocols developed and established?	Process should include: • Standard template, consistent terminology and page numbering • Engage appropriate subject experts • Clear governance arrangements • Clarify who is responsible for accuracy of content • Clearly identify the authors • Define document authorisation process • Identify all primary source data against which checks should be made • Make it clear who has responsibility at every point of the radiotherapy process • Training for staff
How is assurance of service quality provided to the employer?	• Audit of compliance • Systematic analysis of actual or potential AUE • Risk management tools • Regular feedback to governance teams
How are procedures and protocols reviewed?	Process should: • Include clear governance arrangements • Describe the review process to incorporate staff feedback • State who is responsible for document review • Describe version control • Document revision history, summary of changes, approval, date of issue and next review date
How frequently should reviews occur?	• Local decision – commonly every two years or following change in technique or technology, service delivery, legislation and so on based on whichever is the minimum[24]
How and where can staff access procedures and protocols?	• Ensure training is given to staff on use of QMS • Ensure easy access to QMS, for example via: • Read-only electronic documents (available on the intranet, shared network drive or QMS) • Paper documents (to allow access in the event of a network failure; however, multiple, uncontrolled copies of versions should be avoided) • Consider access for staff based outside the department (eg referrers at external clinics)
How are changes communicated to all relevant staff?	Formalised process and may include: • Staff meetings (minutes and attendance list) • Email (with read receipt) • Electronic QMS software notification • Communication with staff based outside the department (eg referrers at outside clinics or interventional radiology staff for selective internal radiotherapy [SIRT])

The employer's QA programme must include a study of the risk of AUE in radiotherapy [Regulation 8(2)]. This is discussed further in Chapter 19.

03

Procedures, document control and audit

IR(ME)R audit

The QA programme should cover all aspects of the radiotherapy process. To ensure that the QA programme is being followed and written procedures are complied with, a system of regular audit is essential. A schedule of audit may be drawn up on a rolling programme to check that employer procedures are in place and being followed. Some examples of IR(ME)R audits are included in Table 3.2 below, but this list is not exhaustive.

As IR(ME)R audits typically measure compliance with the procedures, the target compliance should be set at 100%. This is one aspect where IR(ME)R audits may differ from clinical audits. A blended approach of prospective and retrospective audits may be beneficial to provide assurance in relation to compliance. For example, a retrospective audit of patient records could identify compliance issues, which may be further supported with an observational type of audit (prospective). Following completion of audit, areas for improvement should be addressed within a suitable time frame, with subsequent reaudit scheduled to evaluate the effectiveness of actions taken. It is important that the learning identified via audit is shared with all relevant staff.

03

Procedures, document control and audit

Table 3.2: Considerations when establishing an IR(ME)R audit programme

Audit	Things to consider
Employer's procedures	• Do the employer's procedures meet the requirements of IR(ME)R?
Appropriateness of referrals	• Is the referrer identifiable and working within their corresponding scope of practice? • Does the referrer adhere to the relevant referral guidelines and referral process? • Is sufficient clinical and demographic information provided to justify the referral and identify the patient?
Patient ID procedure	• Is it possible to identify who performed the ID check and are they entitled to do so? • How and where is this recorded? • Is the procedure being complied with by the operators?
Patient pregnancy or breastfeeding status procedure	• Are pregnancy or breastfeeding enquiries carried out and documented in accordance with the employer's procedure and appropriate action taken?
Dose assessment and recording	• Have dose reference levels (DoRLs) been implemented and reviewed as per the employer's procedure? • Are doses or administered activities accurately recorded? • What action is taken where DoRLs are consistently exceeded?
IR(ME)R operator, practitioner or referrer entitlement	• Are records up to date and accurate? • Do they reflect current scope of practice? • Are all duty holders appropriately entitled both within the department and outside?
Operator and practitioner training records	• Are records available and up to date? • Do competency records reflect available equipment and processes?
Justification and authorisation	• Is it possible to identify the practitioner and/or operator authorising? • Is the operator authorising appropriately in accordance with authorisation guidelines?
Clinical evaluation	• Is there evidence of a written clinical evaluation in a sample of patient records for the treatment and concomitant exposures?

03

Procedures, document control and audit

Clinical audit

Regulation 7 requires the employer to have in place a programme for clinical audit. The employer's procedures must detail the process, including the requirement to take appropriate action in relation to the audit results. Clinical audit is a tool for directly improving healthcare outcomes and ensuring patient care is provided in line with best practice standards.[26] Change should be implemented where practice is deemed to fall short of the standard and, after a period of time, reaudited to ensure the corrective action has had the desired positive effect. Audit results should be communicated to all relevant stakeholders.

The general objectives of clinical audit should be to:

- Improve the quality of patient care
- Identify areas for improvement
- Promote the effective use of resources
- Enhance the provision and organisation of clinical services
- Further professional education and training.[27]

Audit will help to identify:

- How well a department is performing against predefined standards or benchmarks
- Areas where performance or compliance is not meeting agreed standards and areas for improvement
- Compliance with existing evidence-based practice
- Areas where training is needed
- Areas where modification of practice is needed
- Where new standards are required.

Scenario 2

As part of an annual clinical audit programme a department includes an audit of practice against national guidelines. The department uses volumetric modulated arc therapy (VMAT) for patients undergoing radical treatment for rectal cancer. A clinical audit is designed by the multiprofessional team involved in the planning and delivery of the treatments. The clinical audit reviews local practice against national guidelines for rectal IMRT.[28] The clinical audit is supported and approved by the employer and implemented prospectively. The data collected are analysed and compared with the national guidelines. This is subsequently shared locally to inform practice and is presented at national multiprofessional meetings to add to the available body of evidence.

03

Procedures, document control and audit

Clinical audit should be an established part of every radiotherapy service and a key component of the wider clinical governance framework. The basis for audit should be to assess the quality improvement process by highlighting the discrepancies between actual practice and standards.[26] It should aim to enhance the provision and organisation of clinical services through the promotion of the effective use of resources and the changes needed to improve the quality of practice.

A multidisciplinary team (MDT) approach to establish and carry out an audit programme will yield the best results. Clinical audit should ideally combine both internal and external assessments or peer review as part of the audit in order to achieve optimal outcomes.[27]

With increasingly complex radiotherapy equipment and techniques, maintaining quality in radiotherapy has to be dynamic and wide-ranging. It must be measured and re-evaluated against best practice standards from peer-reviewed publications and from the wider radiotherapy community, not solely through internal departmental audit. In circumstances where there is limited peer review evidence, departments should endeavour to introduce new techniques with caution and perform prospective audit to provide good-quality data to ensure that the new techniques benefit patient care.

Clinical audit results should be disseminated to all appropriate staff to drive learning. Results should also be used in the engagement, education and training of staff to create an environment of continuing development. A clinical audit report should provide basic information about the audit, display the audit results, provide a plan to implement change and a review date or timeline of when that change should happen. Results of clinical audit should be made available to the employer.

Clinical audits focus on assessing and improving the quality of services by comparing practice against established standards. IR(ME)R audits, on the other hand, enable the employer to specifically assess compliance with written procedures [Regulation 6(2)].

04 Training

Regulation 17(1) prohibits any practitioner or operator from carrying out an exposure or any practical aspect of an exposure without having been adequately trained. Regulation 17(2) defines recognised evidence of training, for example certificates for degrees and diplomas. Schedule 3 lists the theoretical knowledge and practical experience required as adequate training for practitioners and operators.

The employer's responsibility

The employer is responsible for ensuring all practitioners and operators are adequately trained to perform the tasks defined within their scope of practice [Regulation 6(3)(a)]. This includes undertaking CPD education and training after qualification, including when new equipment or techniques are introduced [Regulation 6(3)(b)].

Employers should consider establishing an auditable process for the management and delivery of training within their local governance framework. As individuals join a department, there is often a period of induction into local practice. Time should be allowed for the delivery, receipt and recording of effective training. Regulation 17(4) requires the employer to keep training records for all practitioners and operators and make these available at inspection. Training records should contain the date and the nature of any training and need to reflect an individual's CPD and local department-specific training, as well as that achieved through pre- and post-registration qualifications. The training record should be linked to the individual's scope of practice that they are entitled for. Guidance on compiling training records and an example of a training record for clinical oncologists are included in Appendix 5.

Before operators use a piece of equipment unsupervised, they must complete a training programme and a record should be made of this training, even if they have used the same type and make of equipment at another site. The reason for this is that while some equipment may seem familiar (eg a linear accelerator or TPS), there may be differences in the way it has been commissioned that affect its use.

Training packages may be developed collaboratively across multiple sites or networks. However, these initiatives do not negate the requirement for local training, assessment of competency and entitlement in accordance with documented procedures.

Training is also required in the communication with patients or carers and comforters about the benefits and risks from exposures.

Training records of all staff entitled to act as practitioners and/or operators should be reviewed and updated periodically. This might usefully be done at time of appraisal or when additional training has been successfully completed. This information may be collated in a training matrix that cross-references the duty holder's scope of practice and entitlement.

04

Training

Regulation 17(5) requires employers to co-operate with regard to the training records for locum and agency staff (see Chapter 2 for more on co-operations between employers). The employing agency has the responsibility to check formal qualifications, registration and training of the individual through its own recruitment processes. The employer must be satisfied that the agency employer has systems in place to review and maintain the training records. Training records must be made available to the employer when requested. Local induction training requirements apply as equally to locum and agency staff as to permanent employees.

Adequate training

Schedule 3 of IR(ME)R outlines the areas of theory and practice necessary for the training of practitioners and operators to be considered adequate. It sets out details of the adequate training that practitioners and operators must have completed before they can be entitled by the employer. Areas of training need only reflect the tasks that the duty holder will undertake. Tables 1 and 2 of Schedule 3 were updated as part of the amended regulations.

The subject areas in Schedule 3 (Table 1), as relevant to a practitioner's or operator's role, should be covered in adequate breadth and depth so that an individual may carry out their duties.

Schedule 3 (Table 2) details focused areas of knowledge and training relevant to specific areas of practice (diagnostic radiology, radiotherapy and nuclear medicine). Although formal training programmes will provide adequate education and practical training relevant to each profession, there is scope for further development in many of these areas and a clear need for further training in some. For example, when upgrading a linear accelerator, all relevant staff will need to be trained on how to use the new equipment and associated imaging equipment. Practitioners and operators should consider the need for further training prior to any extension to their scope of practice that crosses the boundary between diagnostic radiography, radiotherapy and nuclear medicine; for example, the use of magnetic resonance imaging (MRI) for radiotherapy planning or treatment verification or use of positron emission tomography computed tomography (PET-CT) as part of the radiotherapy planning process.

Training should not be limited to the operation and optimisation of the equipment but should incorporate the elements of Schedule 3 that govern the particular patient pathway and take into account any statutory and non-statutory requirements of the healthcare practitioner. An example of a non-statutory requirement might be adapting communication techniques where an individual undergoing an exposure is anxious or vulnerable. Operators and practitioners should always demonstrate compassion and act as the individual's advocate where appropriate.[29–34]

As for all IR(ME)R duty holders it is the responsibility of each individual, regardless of their professional background, to recognise and work within the limitations of their own knowledge and skills.

04

Training

Continuing education and training

Regulation 6(3)(b) requires the employer to ensure that all entitled practitioners and operators undertake CPD and training. Such training should be relevant to an individual's role and function and related to any service or role development. In the case of clinical use of new techniques, the employer should ensure training has been undertaken in relation to those techniques and the radiation protection requirements associated with them. Training should be viewed as continuing – the introduction of new equipment, new software or the upgrade of existing software and systems has associated training requirements. To maintain professional registration,[34,35] many individuals are required to demonstrate CPD and maintain appropriate records accordingly. Such records are likely to include evidence of local training, records of attendance at external learning events, additional external qualifications and self-directed learning.

Principles for developing local training records

Practitioner and operator training records are held by individuals as part of requirements for professional registration and are reviewed locally at agreed intervals to ensure they are up to date and support the individual's scope of practice. They should be made available for inspection if requested. Training records for practitioners and operators should be detailed and up to date, reflecting training and competency achieved as they learn different skills.

The link between completion of training and entitlement to act as a duty holder under IR(ME)R should be clear and traceable.

Training records used to support ongoing professional registration or existing local training records used for specific professional groups should be reviewed and used to inform a standard approach where appropriate. For example, training records for clinical scientists or therapeutic radiographers can be used to inform those for clinical oncologists.

Medical staff from other specialties – for example, neurosurgeons who have not had specific training on working with ionising radiation as part of their professional qualifications – may undertake duty holder roles after appropriate theoretical and practical training. Staff must be trained on the equipment they are using and must be able to evidence this. Schedule 3 of IR(ME)R should be used to inform the training package.

Key considerations for developing local training records are included in Table 4.1.

04
Training

Table 4.1: Considerations when developing local training records

Training records	Things to consider
Scope	• Training need only reflect the tasks that the operator or practitioner will undertake. • Training records should be linked to the individual's scope of practice for which they are entitled to act.
Responsibility	• The employer has a responsibility to have systems in place to ensure staff work within their scope of practice. • It is the responsibility of each individual to recognise and work within the limitations of their own knowledge, skills and scope of practice. • Trainers and assessors who sign off training records should be recognised locally as subject matter experts with the appropriate approval to undertake this task.
Records	• Records should be signed by the individual undergoing training and the trainer/assessor. • Training should be provided prior to role extension. • The date of local department-specific training (initial training, review dates and refresher training dates) should be included. • Training records should reflect an individual's CPD as well as that achieved through pre- and post-registration qualifications. • In the case of clinical use of new techniques, training must be undertaken related to new techniques and relevant radiation protection requirements. The detail or description of training should be available for reference. • Additional records will be required where individuals work across more than one site/provider, especially where protocols, procedures, processes, equipment, techniques or commissioning differ.
Review	• Training records should be reviewed at the time of appraisal or at a locally agreed frequency by the service lead, clinical director or IR(ME)R lead. • Where individual duty holders have experienced a long-term absence – for example, sickness or parental leave – refresher training should be considered prior to resumption of clinical duties.

Practitioner training records

Professional qualifications in clinical oncology, for example Fellowship of The Royal College of Radiologists (FRCR) by examination and the subsequent Certificate of Completion of Training (CCT) as approved by the General Medical Council or equivalent thereof through the Certificate of Eligibility of Specialist Registration (CESR) route, are suitable for use as evidence of competence to act as a practitioner for both treatment and concomitant exposures.

04

Training

Practitioners in MRT and brachytherapy require a valid licence issued by the licensing authority to be able to justify an exposure involving the administration of radioactive substances [Regulation 5(1)(b)].[36,37] The Administration of Radioactive Substances Advisory Committee (ARSAC) *Notes for Guidance* details training requirements for inclusion in a new practitioner licence application. This includes numbers of procedures undertaken in the previous 12 months, attendance at relevant training courses, requirement for CPD and linking an individual's training record to their scope of practice.[36] The practitioner licence is issued on the basis of specialist training and experience.[36] This may be further guided by recognition of site specialisation, and entitlement should be appropriate to the skills and level of training and experience of the individual.

Scenario 3

A consultant radiographer specialising in palliative radiotherapy underwent training consistent with the core curriculum for FRCR Part 1 and was able to evidence this to the employer. This included completion of some RCR training courses, M-Level HEI modules, local shadowing of a consultant clinical oncologist and MPE and completion of a number of case studies assessed by the local MDT.

This was recorded in their local training records. They were subsequently entitled as a practitioner within a defined scope of practice. The consultant radiographer's defined scope of practice includes:

- The justification and authorisation of palliative CT planning exposures for bone metastases
- The justification and authorisation of palliative treatments for bone metastases including associated on-treatment verification imaging as defined in local protocol
- Approval of palliative radiotherapy treatment plans for bone metastases in accordance with the local palliative radiotherapy clinical protocol.

Employer's procedures should specify comparable training requirements for any IR(ME)R practitioners who are either not medically qualified, such as radiographers, or medically qualified but not part of a training programme that includes working with ionising radiation, for example associate specialist doctors.

The training records should demonstrate appropriate skills, knowledge, experience and assessed competence within a clearly defined scope of practice. SCoR has provided guidance on what should be included for non-medically qualified IR(ME)R practitioner training.[38] It should be noted that imaging in radiotherapy is always associated with a course of treatment, so any justification of imaging should include a consideration of the benefits of accurate delivery of that treatment, along with the risks of the total dose received by both imaging and treatment exposures. Therefore, the treatment practitioner will usually be best placed to make this decision.

04

Training

Operator training records

All healthcare professionals, including doctors, APs and MPEs, acting as operators must have training records that reflect their scope of practice and are periodically updated for each piece of equipment and for similar equipment across different sites.

Some elements of the training records may be included in department induction processes. Equipment training records are often held centrally for all professional groups as part of the online QA system. A certificate can be issued to individual operators to outline their scope of practice as an operator and made available for inspection if requested. Evidence of regular IR(ME)R refresher training as part of operator training records is a helpful indicator that individuals are aware of their responsibilities under IR(ME)R. Additional training that should be recorded could include:

- Software systems used for volume and organ delineation
- Software systems used for plan evaluation and authorisation
- Image review and evaluation software used for image fusion as part of planning or verification.

Operator training is usually provided by the subject matter expert – for example, training on the use of the TPS by the MPE or dosimetrist, or training on verification image matching by the imaging lead.

Proof of adequate initial training for radiographers and clinical scientists will be provided by an appropriate qualification leading to registration with the HCPC. For clinical oncologists, proof of adequate initial training will be provided by their medical training supplemented by specialty training resulting in attainment of a CCT. This should be reflected in the employer's procedures.

MPEs must also be appropriately entitled as IR(ME)R operators for specific tasks and keep an up-to-date record of their knowledge and training. An individual can only be entitled as an MPE if they are recognised by the Secretary of State in Great Britain, or the Department of Health in Northern Ireland. The Department of Health and Social Care has established a UK-wide MPE recognition scheme and appointed RPA2000 as the assessing body.[39,40] The employer must appoint suitable MPEs and ensure they are involved to the extent required by Regulation 14(2) and 14(3). This includes the training of practitioners, operators and other staff in relevant aspects of radiation protection [Regulation 14(3)(h)].

Each MPE's scope of practice may be limited to external beam radiotherapy, brachytherapy, MRT or a combination of the three. Close collaboration between MPEs is essential. Alternatively, they may be an MPE with expertise in both radiotherapy and diagnostic imaging. They will require local training and induction prior to entitlement, but their capability to act as an MPE will usually be assessed during recruitment. Some staff may achieve national recognition during their employment (through portfolio assessment or equivalence), and the employer may well choose to appoint them as an MPE at this point.

It is the responsibility of the MPE to recognise and work within the limitations of their knowledge and skills. MPEs should be included with other operators in training undertaken by a manufacturer's applications specialist when new equipment is installed. The MPE will continue to develop their knowledge and understanding of equipment performance, for example by working with engineers and applications specialists during planned upgrades or installations. See Chapter 17 for further information on the role of MPEs.

04

Training

Scenario 4

A clinical oncologist is entitled to act as a referrer, practitioner and operator within a defined scope of practice. They receive appropriate training and assessment of competency before they are entitled to act within their practitioner and operator roles. Their scope of practice for their entitled operator role includes the following tasks:

- Patient identification
- Checking pregnancy or breastfeeding status
- Outlining of target volumes for palliative, breast and prostate anatomical sites in accordance with departmental protocols
- Peer review of target volumes for palliative, breast and prostate
- Authorisation of the treatment plan for palliative, breast and prostate anatomical sites in accordance with departmental protocols
- Clinical evaluation
- Clinical patient review.

The clinical oncologist maintains their individual training record, which includes details of their training, assessment of competency, CPD, entitlement and corresponding scope of practice. Their scope of practice is reviewed annually during their appraisal.

Medical staff from other specialties, for example neurosurgeons who have not had specific training on working with ionising radiation as part of their professional qualifications, may undertake operator roles after appropriate theoretical and practical training. Trainees who are not registered healthcare professionals, such as medical students, must be supervised by an appropriately trained and entitled operator. Further detail can be found in the 'Supervision including students and trainees' section, below.

Supervision including students and trainees

Regulation 2 defines an operator as any person who is adequately trained to carry out practical aspects of an exposure and differentiates this from anyone who acts under the direct supervision of a person who is adequately trained.

Where an individual is not considered adequately trained and therefore cannot be entitled as an operator, they must be supervised by someone who is entitled to undertake the task.

An operator who supervises a trainee may provide evidence that the trainee has successfully completed training, including theoretical knowledge and practical experience, to be deemed adequately trained and competent. However, it is for the employer to decide whether or not an individual is consequently entitled to act as an operator. For further information see Chapter 5.

A trainee (eg a student radiographer or trainee AP) is unlikely to meet the requirements of Schedule 3 on adequate training to be entitled as an operator until they have completed a full programme of assessment. Until this time Regulation 17(3) applies. This allows trainees to perform any practical aspect of an exposure under supervision. In this situation, the supervising operator retains full responsibility for each task. It is essential that the supervisor has agreed to oversee a particular task before it commences, and that the trainee is clear who is supervising them.

04

Training

There is guidance available from the professional bodies on what constitutes adequate supervision of trainees.[13,41,42] Inappropriate supervision arrangements may put the patient or individual at risk. The same level of care and supervision should apply throughout normal working hours and out of hours.

An employer may entitle a trainee undergoing practical training as an operator within a clearly defined and limited scope of practice. An agreed level of competence should be recorded and assessment should be undertaken in collaboration with the associated educational institution.

For trainee clinical oncologists, who will already be medically qualified but still undertaking training in preparation for the final FRCR examination, the scope of their entitlement, as both practitioner and operator, should be commensurate with their training, knowledge and experience. This may be extended as they progress through their training. There should be clarity as to which aspects of their role require supervision.

Training for referrers

While not explicitly required under IR(ME)R, it is considered best practice that, where practicable, referrers complete some form of local awareness training. The scope of training may include:

- Knowledge of the radiation exposure requested
- Use of the electronic referral system
- How to request, cancel or change a referral (electronic and/or paper)
- Local procedures governing the use of IT and GDPR, including any potential for disciplinary action if log-in details are shared
- How to access the referral guidelines, including information on radiation dose
- The specific exposures included in a non-medical referrer's entitled scope of practice
- Professional and legal responsibilities.

An organisation may deem it appropriate to entitle some referrers, for a limited scope of practice, to specific areas of anatomy or types of exposures.

Joint professional body guidance is available for referrers who are not medically qualified, for example radiographers.[43,44] Employers should ensure appropriateness of referrals for examinations involving the use of ionising radiation through regular audit. This should be part of an overarching radiation protection governance and assurance programme that promotes education and service improvement. Referral processes are discussed further in Chapter 6 and use of electronic signatures is discussed further in Chapter 2.

04

Training

Training for non-IR(ME)R duty holders involved in the referral process

Some of the initial receipt and processing of referrals may fall to non-IR(ME)R duty holders such as administrative staff. Consideration should be given to the training of these staff to ensure referrals are actioned in a timely and consistent manner. This should include, for example, familiarisation with the referral procedure to:

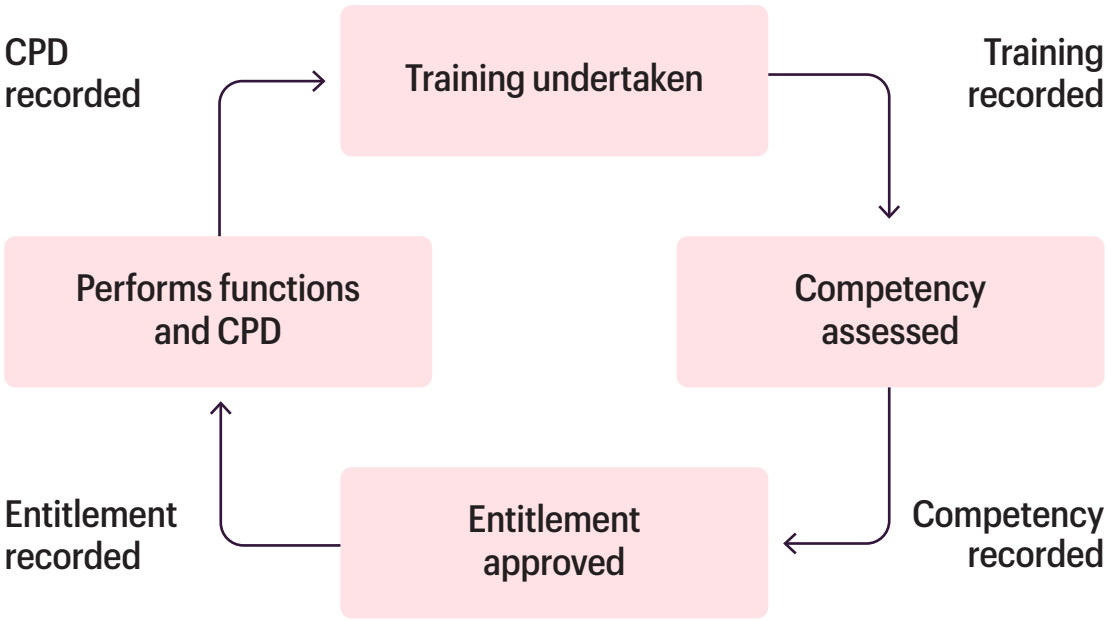
- Alert the referrer when additional information is required
- Alert the referrer that an exposure has not been justified
- Alert the referrer that a patient is not contactable
- Ensure referrals are appropriately prioritised and expedited as required
- Manage future appointments at specific time intervals, for example commencement of external beam radiotherapy for prostate cancer three months after hormone therapy
- Address patient queries regarding their examination.

Referral processes are discussed further in Chapter 6 and use of electronic signatures is discussed further in Chapter 2.

05 Entitlement

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within the organisation. They must have the knowledge and experience to approve, on behalf of the employer, that a duty holder or a group of duty holders has been adequately trained and deemed competent in their specific IR(ME)R duty holder roles.

Figure 5.1. The process of entitlement



The process of entitlement is shown in Figure 5.1 and is described as follows:

- Training supported by training records
- Assessment of competence by an appropriate individual – this must be documented
- Entitlement – this may be for an individual or by staff group (when practicable)
- Duty holder performs their functions and undertakes CPD.

The employer has the responsibility to ensure that all practitioners and operators are adequately trained to perform the tasks defined within their scope of practice [Regulation 6(3)(a)]. Training requirements are described in further detail in Chapter 4.

There is a requirement to have an employer's procedure that identifies individuals entitled to act as IR(ME)R duty holders [Schedule 2(b)]. Examples of entitlement matrices can be seen in Appendix 6. Table 5.1 includes matters to consider for inclusion within the employer's procedure required under Schedule 2(b).

05
Entitlement

Table 5.1: Points to consider for inclusion in employer's procedure under Schedule 2(b)

Entitlement procedure	Things to consider
Who has responsibility for compliance with IR(ME)R in the organisation?	• Statement to identify the employer and their responsibilities under IR(ME)R
Lines of IR(ME)R accountability and delegation of tasks throughout the organisation	• Clear governance structure • Ensuring tasks are delegated to appropriate individuals • Clear lines of escalation to the employer, where appropriate • Those using ionising radiation or performing duty holder roles outside the local radiotherapy or nuclear medicine department
Responsibilities of IR(ME)R duty holders	• For referrers, practitioners and operators, reading and complying with the relevant employer's procedures [Regulation 6(2)] • Do staff understand what duty holder roles they are performing and when?
Initial qualification requirements for each duty holder/group of duty holders	• Relevant qualifications (eg FRCR Part 1 for clinical oncologists, BSc (Hons) or equivalent for radiographers, MSc for clinical scientists) (see Chapter 4) • Who is responsible for checking relevant qualifications prior to entitlement?
Confirmation of registration for referrers and practitioners	• Process for checking individuals are registered healthcare professionals as defined in the National Health Service Reform and Health Care Professions Act 2002[45]
Confirmation of practitioner licence for administration of radioactive substances	• Records of valid licences and process for renewal before expiry (see Chapter 20)
How individuals/groups demonstrate their entitlement and scope of practice	• Documents, entitlement letters or software showing scope of practice and identifying the individual entitled
How entitlement/scope of practice is updated and reviewed	• Process for reviewing and updating entitlement/scope of practice • Specified time frame (eg at appraisal or when scope of practice changes) • Who is responsible for auditing and reviewing entitlement/scope of practice
How non-substantive staff are entitled (eg agency staff)	• Process to confirm training and registration where appropriate (see Chapter 2 for co-operation between employers) • All of the above where relevant

05

Entitlement

The organisation should designate an accountable representative to ensure the employer's duties are fulfilled. A statement should be included to clearly define this responsibility, such as: 'The overall responsibility for ensuring that the Ionising Radiation (Medical Exposure) Regulations are complied with lies with …'.

The employer's procedure should unambiguously describe who has been delegated the task of ensuring duty holders, throughout the organisation, are appropriately trained, competent and entitled to perform their roles and how this is achieved. It should describe the governance arrangements for approving entitlement, detailing how entitlement is managed and the roles and responsibilities of those involved. A description of IR(ME)R lines of accountability can be evidenced through supplementary organisational charts within the employer's procedure.

Where staff are entitled as a group, the employer must be able to identify each individual in that group. The individuals must be trained, assessed for competence and entitled before performing the task and have a means of demonstrating their entitlement and scope of practice. This may be demonstrated through a letter or entitlement matrix provided by the employer.

It is important to emphasise that, while the task of training, assessing and entitling may be delegated, the legal responsibility always remains with the IR(ME)R employer. The employer's procedure should identify those who are authorised to assess and confirm adequate training and experience for each of the competencies that are included in the scope of entitlement.

The procedure must also incorporate those duty holders and areas outside of the local radiotherapy department using ionising radiation, for example intraoperative radiation therapy (IORT) or SIRT. There may be different management structures and lines of accountability in these departments.

Regulation 5(1)(b) requires practitioners who justify exposures involving the administration of radioactive substances to hold a licence. When entitling practitioners for brachytherapy and MRT procedures, the employer should also ensure that the individual holds a valid practitioner licence. Further information on licensing is included in Chapter 20.

Each duty holder, or group of duty holders, will have a defined scope of practice that clearly describes the extent of the tasks they may undertake.

Scope of practice

A scope of practice describes a range of tasks based on professional registration, education, training, knowledge and experience. It encompasses the competencies and training required to perform specific tasks to ensure safe and effective practice.

Each duty holder should have a scope of practice outlining the tasks they are entitled to perform, and they should be clear about what they are allowed to undertake. This scope of practice should be updated when, for example, there is a new service requirement or an installation or upgrade of equipment, or when a scope of practice has been extended in some way. This also applies when a duty holder is no longer involved in a task or has had a significant period of absence and where refresher training is required. As part of the appraisal process, the scope of practice and associated training records of all staff entitled to act as practitioners and/or operators should be reviewed and updated.

The scope of practice may be very limited and specific. For example, an AP working on a treatment unit is entitled as an IR(ME)R operator to set up specified groups of patients for treatment, or clinical oncology consultants are entitled as IR(ME)R operators to outline clinical target volume (CTVs) and organs at risk (OAR) for specified groups of patients in the TPS.

05

Entitlement

There should be a process to sign off training records at each stage to confirm assessment of competence by the assessor and the employee. A competency assessor should be familiar with, and experienced in, the tasks and requirements of the duties they are assessing. Table 5.2 includes further matters to be considered when establishing employer's procedures on entitlement.

Table 5.2: Considerations for entitlement

Professional roles and duty holders	Things to consider
Assistant practitioner or clinical technologist trained to perform some of the practical aspects of radiotherapy treatment delivery for a defined scope of practice **Entitle as an operator**	• Training programme and records[46,47] • Audit of practice
Medical physics expert (MPE) **Entitle as an operator**	• Where MPE advice is provided under contract, the MPE must be entitled by each employer (see Chapter 2)
Professional groups outside radiotherapy For example, breast or colorectal surgeon using IORT device or neurosurgeon involved in stereotactic treatments **Consider entitlement as referrer, practitioner and/or operator**	• Training programme including specific IR(ME)R/radiation protection training • Up-to-date records (see Chapter 4) • Defined scope of practice • Appropriate registration for referrer and practitioner entitlement • Audit of practice
Third-party provider undertaking planning (dosimetry) or delivering the radiotherapy treatment **Entitle as an operator**	• Qualifications, registration and appropriate training checked, and records available (maintained by third-party provider) • Training records should be made available to the employer by the third-party provider on request • Audit of practice • Review detail of contract to ensure IR(ME)R requirements are met and responsibilities are clearly defined for each aspect of the care pathway (see Chapter 2)
Agency staff **Consider entitlement as an operator, referrer and/or practitioner depending on professional background within a defined scope of practice**	• Qualifications, training and registration checked (see Chapter 2 for co-operation between employers) • Induction programme should include training records for locally delivered training • Agency should be able to provide up-to-date training records upon request • Audit of practice

06 Referral process

A referral is a request for an exposure to be performed, not a direction to undertake an exposure. A referral must be made by an appropriately entitled registered healthcare professional as defined by IR(ME)R (see Chapter 2). See Chapter 21 for further considerations on referral for research exposures.

Duty holders have responsibilities relating to the referral process under IR(ME)R at each step of the patient pathway. These are included in Table 6.1.

Table 6.1: Considerations for the referral process

Regulation	Things to consider
Employers must establish referral guidelines, including doses, and make these available to referrers Regulation 6(5)(a)	• Use evidence-based data, where available, for the development of referral guidelines • Referral guidelines should be included in treatment site-specific clinical protocols • Include dose estimates for concomitant exposures and treatment prescriptions in treatment protocols • Process to ensure all referrers have access to referral guidelines (including referrers external to the organisation)
Employers must establish an employer's procedure for the making, amending and cancelling of a referral Regulation 6 Schedule 2(p)	• Outline how referrals are made; this can be paper based or through use of electronic systems, and consider mandatory fields to reduce incomplete referrals • Communication process for amending and cancelling referrals • Management of incomplete or incorrect referrals • Process to ensure referrers recognise any limitations due to their scope of practice and understand how this aligns to their responsibilities under IR(ME)R • Referral process for standard and additional planning and verification exposures • Requirements for referrer awareness training if applicable
Referrer must comply with the employer's procedures Regulation 10(1)	• Process to ensure all referrers have access to the employer's procedures (including referrers external to the organisation) • Audit quality of referrals against referral guidelines (including shared learning)

06

Referral process

Referrer must supply sufficient medical data for practitioner to enable justification Regulation 10(5)	Information that could be required on a referral: • Accurate, current patient demographics • Confirmed clinical diagnosis (eg confirmed histology and imaging report) • Relevant clinical history (including previous radiotherapy) • Referrer name, contact details and signature • Timing of treatment • Information related to pregnancy and breastfeeding (where relevant) • Date of referral completion • Information related to research trial (where relevant) • Mobility status (eg requires hoist) • Co-morbidities (where relevant) • Other relevant radiation protection information Radiotherapy-specific requirements: • Treatment intent (palliative or radical) • Anatomical site (to include laterality) • Planning scan protocol • Treatment planning approach (field configuration) • Type of radiation and energy • Dose and fractionation MRT-specific requirements: • Prescribed activity • Patient weight when required to calculate prescribed activity • Dosimetry requirements, including post-administration imaging • Relevant information for radiation protection purposes (eg incontinence, self-caring, young children) • Carer or comforter requirements for the administration of radioactive substances • Medication where relevant
Practitioner must consider information supplied by the referrer to justify each individual exposure and avoid unnecessary exposures Regulation 11(4)	• Process for contacting referrer • Documentation of discussions with referrer • Process for declining, cancelling or amending referrals • Signature of practitioner

06

Referral process

Referrals come via a number of routes including the MDT, follow-ups in clinic, image-guided radiotherapy (IGRT) review and ward rounds. The term 'referral' is well understood in the context of one healthcare professional requesting a colleague take forward the management of a patient based on either a confirmed or suspected diagnosis. This may be considered a 'medical referral'.

Where a patient is reviewed by a clinical oncologist or as part of an MDTM and a radiotherapy request or booking form completed, this might be considered a referral under IR(ME)R. This request for a patient to be exposed to ionising radiation constitutes a 'referral under IR(ME)R'. This is particularly pertinent when patients are referred between radiotherapy centres for specialist radiotherapy services.

Referral guidelines

Referral guidelines set out the conditions in which an individual would typically be referred for a specific type of exposure and must include an estimate or indication of the radiation dose associated with that exposure. This requirement extends to the range of exposures conducted in radiotherapy (planning, verification and treatment).

In radiotherapy, referral guidelines are commonly developed as clinical protocols and MDT patient pathways, supplemented by local departmental protocols for urgent and palliative treatments.

In establishing the referral guidelines, it is recommended to consult and agree these with professionals involved in the types of exposures included (eg site specialist clinical oncologists). The employer should also recognise that referral guidelines cannot be written for every clinical situation and they should entitle suitably knowledgeable individuals to refer for radiotherapy in those cases. It might be appropriate to limit this to consultant staff.

Referral guidelines should reflect the range of exposures undertaken in radiotherapy. These include planning, verification, treatment, research and repeat exposures. It is recommended that referral guidelines for therapy and planning exposures include requirements for confirming disease by specific criteria such as imaging or histopathology.

Common approaches to referral guidelines are described below.

- Referral for radiotherapy includes a package of planning, treatment and verification exposures. The package of exposures is described in the relevant site-specific clinical protocol. The referral is for the package of exposures associated with the radiotherapy pathway. The referral is carried out at the beginning of the radiotherapy pathway by an entitled registered healthcare professional, often a clinical oncologist, who also acts as the practitioner for the package of exposures.
- Planning and verification exposures are defined in an imaging protocol, which may include both standard frequencies (eg daily) and additional images that may be acquired for optimisation purposes without additional justification. Registered healthcare professionals, such as therapeutic radiographers, are then entitled to refer for additional verification or replanning exposures, for the conditions described in the imaging protocol (eg patient set-up or technical issues).
- Registered healthcare professionals are entitled by the employer to refer patients for additional planning and verification exposures. For example, when additional imaging is required beyond what is specified in the imaging protocols.

Whichever approach is adopted locally, the requirements above and those in Table 6.1 must be addressed.

06
Referral process

Employer's procedures

The referrer must comply with the employer's procedures [Regulation 10(1)]. The employer has responsibility for putting referral guidelines in place and making sure these are available to referrers [Regulation 6(5)(a)]. The employer must ensure that the current versions of the employer's procedures are made available to all referrers, including those external to the organisation, for example at outlying clinics run remotely from the local clinical service.

There should be a process to ensure referrers understand their responsibilities under IR(ME)R and the employer's procedures. Audit may be helpful to monitor compliance with the employer's procedures.

Schedule 2(p) requires a procedure that outlines how referrals are made, amended and cancelled. This procedure may detail the responsibilities of the referrer, how referrals are made, what information must be included, how referrals can be amended or cancelled and the appropriate communication requirements.

Information required for a referral

The referrer must supply accurate, up-to-date information to enable the operator to correctly identify the individual to be exposed.

IR(ME)R requires that the referrer provides the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the medical exposure to inform the justification process under Regulation 10(5). It is essential that the referrer provides sufficient clinical data so that the exposure can be justified. A radiotherapy treatment referral should include details of, where appropriate:

- Diagnosis
- Diagnostic imaging
- Histology
- How clinical findings and staging examinations will be made available
- Laterality
- Previous radiotherapy where applicable.

Patient referrals for radical radiotherapy must include a diagnosis confirmed by histopathology and diagnostic imaging. Where histology is not possible, and in the cases of patients referred for palliative radiotherapy, it may be more appropriate to confirm diagnosis by diagnostic imaging and physical examination. This required information should be included in clinical protocols specified by anatomical site. Primary source data must be used. The primary source documents or copies should be available throughout the radiotherapy process, particularly at critical points such as planning and prescription.

06

Referral process

Scenario 5

The clinical oncologist (operator and practitioner) is called to the planning room to outline a left tonsil clinical target volume (CTV) and to complete the prescription for treatment. The histopathology report and magnetic resonance imaging (MRI) scans are not available in the planning room as required by the local referral criteria. The PACS and radiological information system (RIS) are unavailable due to a local IT network failure. While the responsibility remains with the referrer to make these available, the duty holders need to work with the employer to resolve this situation. The patient's treatment is not planned until the primary source data are available.

Patient referrals for additional planning or verification images outside those included in local protocols should include relevant clinical information to allow the practitioner to justify the exposure. The written procedures should describe how this is carried out and how it is documented and identify individuals entitled to act as referrers.

Patient referrals for MRT must include the above information and additional relevant information required by the practitioner to justify the exposure, such as medication that may affect uptake of the radiopharmaceutical, relevant radiation protection information such as incontinence or young children at home, post-administration imaging and dosimetry requirements.

The local procedure for completing referral data could incorporate the requirement for medical information about likely fertility where relevant. If the intention is to palliate symptoms of advanced disease in a young person rendered infertile by chemotherapy, then local protocols could reflect how to approach this situation. For example, the responsible clinician could sign to say that questioning regarding fertility is not appropriate.

The employer must entitle individuals to act as referrers for radiotherapy for a defined scope of practice. The entitled referrer should be identifiable on referrals originating from MDTM. Good practice ensures that the clinical oncologist is involved in the MDTM.

Referrer training

While not explicitly required under IR(ME)R, it is considered best practice that, where practicable, referrers complete some form of local awareness training. A resource to encourage referrers to pause and check prior to making a referral was introduced in 2017.[48] This highlights some key checks that should be undertaken as part of the referral process.

Some of the initial receipt and processing of referrals may also fall to non-IR(ME)R duty holders such as administrative staff. More details on referrer training can be found in Chapter 4.

06

Referral process

Referral systems

Electronic referral systems have been widely adopted. However, some employers still accept handwritten referrals from a number of specified sources and therefore run a dual electronic and paper referral system. These different systems should be clearly described in the employer's procedures.

Electronic referral systems and paper-based systems should be fit for purpose to ensure those tasked with referral, administration, justification, authorisation and practical aspects of the referral to therapy pathway can fulfil their responsibilities. It is important the referrer is clearly identifiable, regardless of the type of system in use. Where the initial receipt and processing of referrals is undertaken by non-IR(ME)R duty holders such as administrative staff, consideration should be given to relevant training requirements. This includes ensuring referrals are actioned in a timely and consistent manner and the identification of incomplete or duplicate referrals.

The increased efficiency seen from using an electronic referral system must be balanced with the potential for the incorrect patient exposure requests. Electronic referral systems require the referrer to log in using a unique identifier. Guidance from the RCR suggests that an employer's procedure should ensure it is a disciplinary offence to use someone else's log-in to initiate a referral.[49] The employer's procedure should address potential safety risks when using paper or electronic referral forms.

The main laws governing electronic signatures are the Electronic Communications Act 2000[50] and the Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (eIDAS).[51] These regulations provide a framework for secure electronic transactions and the electronic signature used should meet these requirements.

Employers should ensure appropriateness and accuracy of referrals for medical exposures through regular audit. This should be part of an overarching radiation protection governance and assurance programme that promotes education and service improvement. Inappropriate referrals should be rejected and discussed with the referrer. Additional referrer awareness training should be considered in these cases, and if inappropriate referrals persist, the referrer's scope of practice and entitlement should be reviewed and revoked if required. Audit is an effective tool to evaluate the quality and accuracy of referrals and can help to identify referrer training needs.

07 Justification and authorisation

Justification and authorisation are two separate processes and must be completed for every exposure.

Justification

Justification is the intellectual process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose for that individual.

For radiotherapy these will include planning, verification, treatment and research exposures. For molecular radiotherapy these include treatment, post-therapy single photon emission computed tomography (SPECT) CT imaging and exposures to carers and comforters. Carers and comforters are considered in Chapter 16. Justification can only be completed by a suitably entitled IR(ME)R practitioner.

Regulation 11(1)(b) says that an exposure may not be carried out unless it has been justified, prior to the exposure, by a practitioner, who must ensure there is a net benefit. Where the exposure involves the administration of radioactive substances, Regulation 11(1)(a) says that justification may not be carried out unless the employer and practitioner hold appropriate licences to undertake the intended exposure.

For radiotherapy, the potential therapeutic benefit and detriment of the treatment or concomitant exposure 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, treatment delivery, verification techniques and previous exposure. The detriment to be considered includes long-term and short-term side-effects.

For molecular radiotherapy, justification should take into account the choice of radio-pharmaceutical, administered activity, radiobiological characteristics and, where possible, patient-specific dosimetry, as well as organ function and prior radionuclide therapies. The practitioner should ensure that the intended activity and delivery protocol provide a net clinical benefit while minimising unnecessary radiation to non-target tissues. Consideration should also be given to potential radiation exposure to carers, comforters and the public arising from the patient; while the control of such exposures is addressed under the Ionising Radiations Regulations (IRR) 2017,[52] awareness of them supports appropriate justification and optimisation under IRMER.

Where molecular radiotherapy includes hybrid imaging (eg SPECT/CT or PET/CT) for post-therapy imaging or dosimetry, the CT component constitutes a separate medical exposure and must be individually justified in accordance with its clinical purpose. Where the CT is performed solely for attenuation correction or anatomical localisation, the exposure should be optimised accordingly and recorded as part of the MRT procedure; where diagnostic information is sought, a diagnostic-level justification and authorisation are required.

07

Justification and authorisation

When justifying an exposure, there are a number of considerations for practitioners to take into account including the data supplied by the referrer. For example:

- Has the referrer provided enough relevant clinical information to be able to justify the exposure?
- Has the referrer provided enough information to be able to definitively identify the patient?
- Will the treatment control disease or alleviate symptoms?
- Are there alternative options that do not involve ionising radiation?

Alternative exposures and techniques can be considered at the tumour-specific MDTM.

Particular consideration should be given to risk 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. This is discussed further in Chapter 13.

The other significant consideration is of carcinogenesis. Calculation of lifetime risk is complicated but there have been publications that attempt to address this issue.[6,53–59] The risks vary with the part of the body irradiated and with the dose. In addition, some individuals may have a genetic predisposition to carcinogenesis by radiotherapy. Children and young people are more sensitive to radiation exposure than adults, primarily due to their rapidly developing organs and longer life expectancy.[60] They will therefore require special consideration. This is discussed further in Chapter 15.

Most radiotherapy patients in the UK are treated for malignancies but some are treated for benign disease and these require careful consideration with regard to potential cancer induction.

For radiotherapy, these considerations form an important part of the consent process, and further information can be found in Chapter 14. It should be noted that consent itself is not included in IR(ME)R.

Radiotherapy is an effective and appropriate curative or palliative anticancer treatment for many patients. There are clear benefits that should also be considered as part of the justification process.

Specific matters that must be considered by the practitioner when justifying an exposure are outlined in Table 7.1.

07

Justification and authorisation

Table 7.1: Considerations for justification of an exposure to ionising radiation

IR(ME)R Regulation 11(2)	Things to consider
a) The specific objectives of the exposure and the characteristics of the individual involved	• What is to be gained by carrying out the exposure? • How may the outcome affect the care pathway/ management of the individual? • Has the individual had previous radiotherapy treatment? • The stage of malignancy, medical history, age, pregnancy or breastfeeding status • For unsealed radionuclide exposures, any medication the patient is taking and whether this will affect the result of the investigation; medication may need to be stopped prior to the therapy
b) The total potential therapeutic benefits to the individual	• What is the expected benefit of the exposure? • Can the treatment control disease or alleviate symptoms? • Will the individual's overall treatment be altered?
c) The detriment the exposure may cause	• The estimated dose for the treatment exposure and any concomitant exposures (see also Chapter 10) • What is the risk to the individual from that dose? A detailed list of common and rare, long-term and short-term side-effects should be considered • Brachytherapy or MRT patients with caring responsibilities, those who are hospital inpatients or those who may have prolonged close contact with other people after the therapy may require additional radiation protection advice
d) The efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation	• How effective and safe are any alternative techniques compared with the proposed treatment or concomitant exposures? • Is the alternative available locally in a clinically acceptable time frame? • If no effective alternative techniques are available, what is the risk of not having the exposure?

07

Justification and authorisation

Regulation 11(4) requires the practitioner to take note of all the data provided by the referrer in order to ensure that the exposure is appropriate for that individual and to safeguard against unnecessary exposures. In accordance with local referral processes, if the referral has insufficient detail, the practitioner may request further information.

When justifying an exposure, the urgency should also be taken into account [Regulation 11(3)(d)(i)]. For example, if pregnancy cannot be excluded then the practitioner must consider both the individual concerned and their unborn child. The practitioner should consider if treatment can wait until the baby is born. The clinical risk of delaying the exposure should be weighed up against the risk of the exposure. This is further discussed in Chapter 13. MRT is not usually considered for pregnant patients.

When justifying an exposure to an individual who is breastfeeding, the urgency of the nuclear medicine treatment should also be taken into account [Regulation 11(3)(d)(ii)]. Consideration should be given to delaying the treatment until the individual is no longer breastfeeding and lactation has ceased, choosing an alternative radiopharmaceutical that is not secreted in breast milk and ensuring the purity of the radiopharmaceutical. Dose to breast tissue from continued lactation should be considered as part of the justification process. Further guidance is available in Chapter 13.

Authorisation

Authorisation is the documented confirmation that the intellectual activity of justification has taken place and the exposure may be performed.

Authorisation ensures that there is a clear record of the justification decision and may be carried out by either a practitioner or an operator [Regulation 11(1)(c)]. Where the practitioner is not available and the authorisation process is carried out by an operator, they must follow authorisation guidelines issued by the practitioner [Regulation 11(5)].

Authorisation may be demonstrated by, for example, signing or initialling the referral or treatment chart in a predetermined place or by entering an electronic password. The employer's procedures should describe clearly how authorisation is to be demonstrated.

In radiotherapy practice, it is usual for a single practitioner to authorise a package of exposures for an individual patient. This includes initial planning exposures, treatment and verification exposures.

The detail of how authorisation is completed should be reflected in employers' procedures for each type of exposure undertaken.

Authorisation guidelines

Authorisation guidelines are documented criteria that allow suitably trained and competent entitled operators to authorise exposures when the practitioner is not available.

The operator is responsible for authorisation and for following the authorisation guidelines accurately. Authorisation guidelines must be issued by one named practitioner (often this is the site- or modality-specific lead oncologist or lead licensed practitioner for MRT). The practitioner who issues the authorisation guidelines takes responsibility for justification of each individual exposure authorised by operators following these guidelines. If this practitioner leaves the organisation's employment, the guidelines must be reviewed and updated by another practitioner, who then takes the responsibility for the exposures authorised under their guidelines. Authorisation guidelines must be subject to document QA as described in Chapter 3.

07

Justification and authorisation

The authorisation guidelines should reflect current best practice and take into account local service provision. Authorisation guidelines should be clearly written using precise statements that are unambiguous to allow the operator to confirm whether the exposure can be authorised. Authorisation guidelines typically outline the applicable patient cohort (eg adult or paediatric patients), clinical indications or clinical query to be addressed, exclusion criteria and the range of exposures to be undertaken. This might include detail on the exposure techniques and the number of imaging exposures to be taken. Where the details within a referral, or the patient's condition, fall outside the criteria listed in the authorisation guidelines, the operator cannot authorise the exposure or set of exposures. In this scenario, justification and authorisation must be performed by a practitioner.

Where authorisation guidelines are issued, if operators do not follow these guidelines, they are acting outside their entitlement and may be in breach of IR(ME)R. Healthcare professionals can only legally function as practitioners if they are entitled to do so.

Entitlement by the employer offers a level of protection for both the employer and employee; the employer is assured that staff members are working within a defined and agreed scope of practice and the individual staff members cannot be put under pressure to do anything for which they are not entitled or trained.

Scenario 6

A patient is undergoing adaptive external beam radiotherapy for prostate carcinoma on an MR linac. The initial plan and prescription are justified and authorised by the consultant clinical oncologist (practitioner) prior to first treatment.

The patient undergoes daily MR imaging, with image registration and online planning completed by an appropriately trained and entitled operator (dosimetrist, radiographer or physicist). The operator assesses if the online plan meets locally agreed plan criteria/ plan acceptance tolerances or patient specific values approved by the clinical oncologist (practitioner). If the new plan meets criteria then the patient can be treated. If the online plan does not meet the predefined tolerances, this is escalated to the clinical oncologist (practitioner) to review, justify and authorise (approve) the plan.

Authorisation of planning exposures

In practice, authorisation of planning exposures is usually indicated on the radiotherapy referral. This can be achieved by having a nominated signature or electronic password on the radiotherapy referral to clearly indicate the practitioner has authorised the planning exposures.

The task carried out by the practitioner and referrer are different. Although it is common for many clinical oncologists to be entitled to act as both referrer and practitioner, and in practice this will usually be the same person for radiotherapy exposures. There should be an identifiable individual for each task, either in the way a procedure is drafted or by having two separate manual or electronic signatures on the referral form. The roles should be clear and concise in the employer's procedures.

If additional planning exposures are required other than those set out in the local protocol a procedure must be in place specifying how the practitioner will be informed and where this will be recorded.

07

Justification and authorisation

Authorisation of treatment exposures

Authorisation of treatment exposures is usually indicated by the electronic or manual signature included in the prescription and/or plan approval.

Scenario 7

A head and neck cancer patient commenced the radiotherapy pathway. During planning the OAR were outlined utilising AI-based auto-contouring software. The clinical oncologist registrar (operator) subsequently reviewed the OAR contours and outlined the target volume. The OAR and target volume contours were then peer reviewed by the consultant clinical oncologist (operator). The plan including the prescription was approved within the OMS by the consultant clinical oncologist (practitioner). In accordance with local procedures the electronic signature within the OMS indicates the justification and authorisation of the treatment exposure and a defined number of verification images recorded within the head and neck imaging protocol.

Consideration needs to be given to how the anatomical treatment volume (eg left breast) included in the treatment prescription is linked to the outlined treatment volume (PTV) as part of the localisation process. This is often achieved in practice through the same individual completing the prescription and the plan approval.

Scenario 8

A patient has been referred for 177Lu DOTATATE treatment, a procedure included on the employer licence. The licensed practitioner for this treatment is not available at the time of the referral. A nuclear medicine physician does not hold a practitioner licence for this treatment but is appropriately trained and entitled as an operator to authorise these treatments according to authorisation guidelines issued by the licensed practitioner.

Authorisation of verification exposures

In practice verification exposures are usually authorised as part of the treatment prescription or plan approval.

Standard verification exposures undertaken as part of a specific treatment protocol should be considered when the treatment exposures as a whole are justified. The standard verification exposures are then justified by the practitioner who prescribes the treatment. This allows for consideration of additional dose to OAR and the PTV. These standard verification exposures should be defined for a particular anatomical site or technique, for example within local imaging protocols, site-specific clinical protocols or authorisation guidelines. The number of exposures to be taken must not be open-ended and must include a maximum number or associated dose.

07

Justification and authorisation

The standard number of verification exposures usually includes a set number of additional exposures that may be undertaken for the purposes of optimisation. When the operator, often the treatment radiographer, clinically evaluates the verification image and identifies further action is required in accordance with the corresponding imaging protocol, they are optimising the exposure. If additional verification or correction exposures are required other than those set out in the local protocol or authorisation guidelines, a procedure must be in place specifying how the practitioner will be informed and where this will be recorded.

It is good practice for imaging protocols to be approved by the lead oncologist for the particular area. These protocols should be evidence based, reflecting current practice and local equipment.

Scenario 9

A patient has been planned for prostate radiotherapy and a prescription completed by the clinical oncologist (appropriately trained and entitled practitioner, within a clearly defined scope of practice). In accordance with local protocols the prescription includes authorisation of the treatment exposures and verification imaging defined within the local prostate verification imaging protocol. The prostate verification imaging protocol includes a daily image and one additional exposure for correction purposes if required per day. The treatment radiographer (appropriately trained and entitled operator, within a clearly defined scope of practice) identifies a difference in bowel position and gas on the initial image acquired, resulting in the requirement of one additional exposure. The additional exposure is within protocol and is therefore authorised by the clinical oncologist via the treatment prescription. Details of the additional image are annotated in the patient electronic record by the treatment radiographer.

Justification of exposures to comforters and carers

Exposures to carers and comforters require individual justification [Regulation 11(1)(b)]. It is expected that exposures to carers and comforters will not be justified as part of the external beam radiotherapy planning and treatment process and so will not occur. In MRT and some brachytherapy treatments, individuals may be designated as carers and comforters where they provide support and comfort to a patient within a controlled or supervised area during an exposure, or where they are not able or willing to follow the usual radiation protection precautions. Justification and authorisation may be carried out by a practitioner or these exposures may be authorised by an operator following authorisation guidelines. For more details on carers and comforters see Chapter 16.

Regulation 11(3)(b) specifies additional considerations that must be applied to the justification of exposures to carers or comforters. The requirements in both Tables 7.1 and 7.2 must be considered when justifying exposures to carers or comforters.

07

Justification and authorisation

Table 7.2: Additional considerations for an exposure to carers or comforters

Regulation 11(3)(b)	Things to consider
i Any likely health benefits to the patient	• What is the expected benefit of the exposure? • Can the treatment achieve the intended outcome?
ii Any possible benefits to the carer or comforter	• Reassurance that a family member, partner, friend or dependant is receiving medical attention, and will be able to have a medical treatment with their support
iii The detriment the exposure may cause	• What is the likely dose to the carer or comforter from the exposure? • What is the risk to the individual from that dose?

Justification for research exposures

All research exposures must be clearly identified and each research trial must have research ethics committee (REC) approval as described in Chapter 21. Each research exposure still requires individual justification and authorisation.

08 Optimisation

Optimisation is a key principle of the radiation protection framework within IR(ME)R and is required for all medical exposures. Requirements for optimisation of exposures are described in Regulation 12.

The optimisation process is the joint responsibility of the practitioner and operator, with involvement as appropriate from the appointed MPE. It requires a multidisciplinary approach. Effective communication and teamwork between staff groups are essential, including clinical oncologists, nuclear medicine physicians, radiographers, medical physicists and clinical technologists, along with non-radiotherapy staff and manufacturers as appropriate. Optimisation should be reviewed on a regular basis and when practice changes or equipment is updated.

The aim of optimisation for radiotherapy imaging is to achieve the image quality required for the intended purpose, for example treatment planning or verification, using the lowest dose possible. Optimisation is not limited to dose reduction; it requires an understanding of image quality, equipment parameters and their intercorrelation. Therefore, optimisation requires a multidisciplinary approach with input from specialists able to advise on all aspects of the imaging chain.

Scenario 10

A radiotherapy department aimed to optimise planning and verification imaging across the service. Terms of reference were developed detailing membership, roles and responsibilities, annual work programme and meeting frequency. A multidisciplinary optimisation team was established, including clinical oncologists, radiographers and medical physicists with appropriate expertise. Additional specialists joined as required.

The team developed and prioritised a programme of work, with time frames and measurable outcomes. Multiple data sources including audit results, equipment QA, risk assessment and analysis of local and national patient safety events were utilised to prioritise workstreams. The team identified the review and audit of CT planning protocols, coupled with the development of planning dose reference levels as an initial workstream. Regular meetings supported by agendas, effective plans of action and clear communication strategies resulted in the successful accomplishment of the initial workstream.

To achieve this, radiotherapy services may consider the establishment of an MDT of radiation protection champions including MPEs, radiographers and clinical oncologists.[61] The objectives of this optimisation team may be to establish the processes for dose management within the organisation and to evaluate and effectively communicate the outcomes of those processes.

08

Optimisation

For therapeutic exposures, the practitioner must ensure optimisation of both target volumes and normal tissues as described in Regulation 12(2) (see Table 8.1). Operators must select appropriate equipment and methods to ensure doses are as low as reasonably practicable (ALARP) and consistent with the therapeutic purpose [Regulation 12(3)]. While imaging protocols should be developed through a multidisciplinary optimisation process, operators are still required to use their professional judgement to adjust technique and parameters according to the individual patient characteristics. Planned deviations from standard protocols may be recorded as concessions as part of the QMS and used to inform protocol updates as required.

Table 8.1: Considerations for optimisation of therapeutic exposures

Areas of optimisation	
Target volumes (eg gross tumour volume [GTV], PTV)	• Individually planned • Delivery appropriately verified
Non-target volumes and tissues (eg OAR)	• ALARP • Consistent with the intended radiotherapeutic purpose

The MPE should be closely involved in all therapeutic exposures (except standard nuclear medicine therapies), including contributing to the 'optimisation of the radiation protection of patients' [Regulation 14(3)(a)]. This may include advice on, and contribution to, immobilisation, imaging, treatment planning, equipment QA and verification dosimetry. Further guidance on the role of the MPE is given in Chapter 17.

General and specific areas for consideration during optimisation are summarised in Table 8.2, but this list is not exhaustive.

Table 8.2: Areas to consider in optimisation

General areas of optimisation	Things to consider
Protocols Regulation 6(4)	• Written protocols must be in place to describe the appropriate technique for all standard treatment sites • Evidence-based management guidelines and protocols should be developed by the MDT, reflecting published guidance for high-quality care
Clinical audit Regulation 7	• Image quality, technique (eg use of accessory equipment), protocols, doses (including adherence to local protocols and repeat exposures) or image analysis should be audited regularly with outcomes used to inform future processes and training needs. This process should be reflected in local procedures. • Introduction of new procedures and techniques should be audited in a timely manner to ensure optimisation is achieved

08

Optimisation

Equipment Regulation 12(3)	• Appropriate equipment selection • Local staff should work with manufacturers to ensure any new (or updated) equipment, protocol or technique is optimised (eg keeping imaging doses ALARP for the intended purpose) • Equipment and methods should allow evaluation of patient dose/administered activity • Adherence to DoRLs for typical localisation and verification exposures (see Chapter 9)
MPE advice Regulations 14(2)(c) and 14(3)(a)	• MPE should be consulted on optimisation (see Chapter 17 for more details)
Quality assurance (QA) Regulations 6(5), 12(3) and 15(1)	• There are established QA programmes as required for both written procedures and equipment or methods (see Chapters 3 and 18 for more details)
Training Regulation 17(1)	• There is a robust training programme in place to ensure all practitioners and operators are competent and aware of how to optimise exposures for existing, new or updated equipment
Carers and comforters Regulation 6(5)(d)	• Adherence to dose constraints specified in employer's procedures (see Chapter 16)
Medical or biomedical research programmes Regulation 12(4)	• Informed consent to be given by the individual or on their behalf as appropriate (eg for paediatrics or adults with incapacity) (see Chapter 21) • Informed in advance about the risks of the exposure • Establishment of and adherence to relevant dose constraints • Planning of individual target levels of dose by the practitioner with input from the referrer as required
Sealed and unsealed source therapies Regulation 12(7)	• Guidance on limiting dose to others the patient may come into contact with after leaving the department (see Chapters 14 and 16)

08
Optimisation

Regulation 12(8) requires the practitioner and operator to pay particular attention to the optimisation of the points listed in Table 8.3.

Table 8.3: Areas requiring particular attention when optimising exposures

Particular attention when optimising	Things to consider
Exposures of children Regulation 12(8)	• Paediatric radiotherapy is a highly specialised area and should only be performed in specialist centres with appropriately trained staff[62] • Special priority should be given to minimise doses to normal tissues, in order to limit long-term side-effects such as growth inhibition or secondary cancers • Appropriate imaging protocols should be available for a range of sizes and ages • Specific paediatric imaging protocols for nuclear medicine and administered activity scaling • (See Chapter 15 for more details)
Exposures involving high doses Regulation 12(8)	• All exposures related to therapeutic exposures should be considered high dose, including any concomitant exposures
Individuals where pregnancy cannot be excluded Regulation 12(8)	• Consider delaying the exposure or using alternative approaches that do not involve the use of ionising radiation • MPE should advise on potential dose estimates prior to exposure and methods of minimising doses • (See Chapters 7 and 13 for more details)
Individuals who are breastfeeding Regulation 12(8)	• Consider delaying treatment or interruption of breastfeeding • Consider potential breast tissue dose from continued lactation even where breastfeeding has stopped

Individual planning

Treatments using external beam radiotherapy or brachytherapy are individually planned in terms of expected radiation dose. Typically, doses are calculated using a computerised TPS based on dedicated imaging data (eg CT, MRI, PET), or in some cases using data tables of expected doses for simple situations. Optimisation does not mean that all patients require the most complex treatments (eg VMAT, stereotactic body radiotherapy [SBRT]), and simple conformal fields may be sufficient in some cases.

Factors to be considered by the practitioner in optimisation of planning include:

- Patient characteristics such as age, gender and medical history
- Anatomical position of the site of exposure and nearby OAR
- Any previous exposures
- Treatment intent, and related factors such as dose and fractionation.

08
Optimisation

Department of Health and Social Care (DHSC) guidance states:

'For individual planning regarding therapy with unsealed sources, the practitioner is recommended to carry out an assessment of the individual patient, taking into account any established dosimetry techniques, relevant professional guidance and the patient's overall medical condition.[4] *Use of standard activities of radiopharmaceuticals may be appropriate in some cases, where this is consistent with professional guidelines.*'

MRT is usually prescribed as a fixed activity or fixed activity adjusted for body mass or surface area, taking into account other relevant factors such as renal function. In the absence of randomised clinical trial evidence, administered activities are prescribed according to published experience supported by clinical judgement and specialist expertise within the MDT. Other methods of dose prescription, for example to a desired whole-body radiation absorbed dose, are available.

Optimisation of MRT will therefore include:

- Assessment of the individual patient
- Use of established dosimetry techniques (where available), or post-therapy verification imaging if full dosimetry is not available
- Use of standard activities where this is consistent with professional guidance.

Scenario 11

In a clinical trial, a child with metastatic neuroblastoma is to be treated with 177Lu DOTATATE. A baseline 68Ga PET-CT has been performed, which has shown tracer uptake (standardised uptake values [SUV] max) in the tumour deposits significantly greater than liver background, indicating a favourable dose to tumour. After each of four administrations, a series of three SPECT-CT scans is performed and the dose to index tumour deposits is calculated, which confirms this. The dose to the kidneys, the principal organ at risk, is also calculated, to see if there is scope for further treatment without exceeding renal tolerance.

Imaging exposures in radiotherapy

Most patients having external beam radiotherapy or brachytherapy will have imaging exposures for planning and verification as part of their treatment pathway. These exposures are not diagnostic, in the sense of seeking a medical opinion, but are an integral part of delivering the therapeutic exposure accurately. Therefore, optimisation of these exposures should be performed, but commensurate with the therapeutic purpose (which may well differ from an equivalent diagnostic protocol).

Imaging protocols should be optimised locally to ensure doses are ALARP while maintaining adequate image quality for the intended purpose. A multidisciplinary approach to optimisation in the development and ongoing review of imaging protocols should be in place. Optimisation will be undertaken at installation and upgrade of equipment, and at regular intervals based on dose audits.

08

Optimisation

Planning imaging exposures should be undertaken in accordance with local protocol and any deviation should be recorded. The operator should optimise the exposure for the purposes of treatment planning, ensuring that the quality, extent and localisation of the medical exposure are appropriate for the purpose intended. Excessive artifact (eg artificial hip) may be a reason to consider images of insufficient quality for delineation and plan calculation.

Consideration should also be given to optimisation of imaging protocols for other imaging modalities outside of CT when images are acquired solely for the purpose of aiding localisation and delineation of target volumes or OAR in treatment planning, for example planning PET-CT.

As with planning imaging exposures, verification imaging should be undertaken in accordance with local protocols. Strategies and considerations for optimisation of CT planning and cone beam CT (CBCT) verification imaging have been published along with national DoRLs. [63–65]

Scenario 12

A department had been applying the same default maximum scan length to all CBCT acquisitions for verification of pelvic radiotherapy. The image-matching protocol for prostate-only radiotherapy required a soft tissue match focusing on the prostate itself and evaluating the position of the adjacent OAR. A retrospective study was undertaken that determined that the same accuracy in matching could be obtained with a shorter than default scan length, reducing the dose to the healthy tissue outside of the treated volume. The imaging protocol was amended to enable adjustment of scan length at time of acquisition for this cohort of patients.

Radiotherapy departments should establish a typical number of verification imaging exposures expected for each treatment site, both per fraction and per course. It is also recommended to state the maximum number of additional images that can be acquired by operators acting within the imaging protocol or authorisation guidelines, before additional justification is required by the practitioner (see Chapter 7). Allowing for such ‘reasonable repeats’ to optimise imaging and ensure accurate treatment should result in minimal delays, and patients with problematic imaging set-up may be discussed with the clinical oncology team at a suitable time during the treatment course.

For some MRT, uptake of the therapeutic radiopharmaceutical or doses to OAR may be predicted or planned with molecular imaging. Optimisation of these exposures should be performed commensurate with the therapeutic purpose.

09 Diagnostic and dose reference levels (DoRLs)

DoRLs are defined as radiation dose levels in therapeutic practices for typical localisation or verification exposures for groups of standard-sized individuals or standard phantoms for broadly defined types of equipment [Regulation 2(1)]. Analogous to the diagnostic reference levels (DRLs) applied in diagnostic imaging and interventional radiology, DoRLs for concomitant exposures can be a useful tool in the optimisation process and can be used as a method for demonstrating that optimisation has taken place.

DoRLs are benchmarks of patient radiation dose, based on dose indices and where certain variables, such as equipment type, examination and patient size, are standardised to minimise uncertainty. All operators should be familiar with and trained in the appropriate use of DoRLs.

Regulation 6(5)(ca) requires the employer to regularly review and make available to the operator DoRLs for typical localisation and verification exposures with regard to international and national DoRLs and local dose surveys where available.

UK-wide surveys of dose indices for radiotherapy treatment planning scans and cone beam CT (CBCT) for verification imaging have been published and inform national DoRLs, providing a useful comparator for optimisation purposes.[63–65] DoRLs apply to a population, and individual patients should not be compared with the DoRL, nor should DoRLs be used as dose limits. Instead, DoRLs are an essential tool in the optimisation process.[66] They can help to identify issues relating to equipment or practice by highlighting unusually high or low radiation doses. DoRLs are not expected to be consistently exceeded when good or normal practice is applied. They should be used in addition to professional judgement and should not consistently be exceeded in normal practice.

The employer's procedure should detail actions required where DoRLs are consistently exceeded [Regulation 6(7)].

Scenario 13

A department audits the dose recorded for 20 recent breast planning CT scans against local DoRLs. They find that CTDI values are all within the DoRL for this site, but that several of the patients have higher DLP values than the DoRL. When these patients are reviewed, it is discovered that the superior border was being set unnecessarily high in case the patient needed nodal treatment fields, apparently because this was not always clear on the referral. The procedure was refined to require a clearer description of scan levels for nodal treatments and staff training refreshers run to emphasise that scan levels should be reduced for breast-only treatments. The audit was repeated after three months, and all values fell within the DoRLs.

09

Diagnostic and dose reference levels

DoRLs are estimates of patient dose. For radiotherapy treatment planning CT scans dose indices such as computed tomography dose index (CTDIvol) and dose length product (DLP) can be readily recorded from the CT scanner itself (see Chapter 18). These indices are not as readily available for CBCT verification exposures and so direct measurements using CTDI phantoms are recommended. Calculation of approximate doses may be useful to aid the practitioner in weighing the benefits and risks of imaging exposures. Calculation of specific doses to an individual have been performed by some research groups, with the potential of combining such doses with the therapy exposures to assess total dose to target and normal tissues. This is not required routinely as the total concomitant dose from imaging is generally a fraction of the therapy target dose. However, the American Association for Physics in Medicine task group 180 recommends that it is not necessary to include imaging dose in the treatment planning process unless the total per treatment course exceeds 5% of the therapy target dose.[67] Dose estimates for each standard type of exposure should be calculated locally and be available to practitioners and operators.

MRT is usually prescribed as a fixed activity or activity adjusted for body mass or surface area according to the SmPC (summary of product characteristics) for licensed products. Local protocols should specify a tolerance range on the activity to be administered.

National DoRLs (NDoRLs)

NDoRLs reflect UK equipment and practice and are developed through a process established by the UK Health Security Agency (UKHSA) National DRL (NDRL) Working Party.

ARSAC sets national DRLs for diagnostic nuclear medicine procedures. These are the recommended administered activities for standard-sized patients. ARSAC does not set recommended administered activities for therapeutic procedures – this is a matter for the clinical judgement of the responsible licensed practitioner. Where available, clinical guidelines should be taken into consideration for administrations of both sealed and unsealed sources.

National dose surveys or audits may be undertaken by UKHSA or ARSAC, professional bodies or other suitable organisations. Resultant data, suitable as NDoRLs, are presented to the working parties for their consideration.

Local DoRLs (LDoRLs)

Regulation 14(3)(a) requires the MPE to contribute to the application and use of DoRLs. Regular dose audits should be carried out under a local governance programme, including when new equipment is installed and if clinical practice changes, as advised in IPEM guidance. This is most effective when undertaken with advice from the MPE working as part of an MDT. LDoRLs should reflect local practice, equipment and patient cohorts.

The employer's procedure [Schedule 2(f)] should stipulate how LDoRLs are used and reviewed. Patient dose audits at suitable frequencies can be used as part of the review process to identify where LDoRLs are consistently exceeded. The employer's procedure should detail the corrective actions to be taken in these circumstances [Regulation 6(7)].

An employer, with advice from the MPE and MDT, may decide to adopt NDoRLs as its own LDoRLs or, following local dose audits, choose to set its own LDoRLs. An LDoRL should be appropriately set using values from a local dose audit, with an appropriate action level identified.[68] Where an LDoRL is set higher than the NDoRL, based on a local dose audit, this should be justified by the employer. In this scenario, efforts should be made to optimise further, or consideration given to replacement of equipment.

10 Patient dose assessment and recording

Regulation 12(3) describes three key aspects of selecting the appropriate equipment and methods to ensure optimisation of exposures: equipment QA (see Chapter 18), DoRLs (see Chapter 9) and assessment and evaluation of patient dose or administered activity. There must be an employer's procedure for this assessment process [Schedule 2(e)]. It should specify what information needs to be recorded. This may be different for each modality and can vary from one manufacturer to another. The employer's procedure should also specify where the dose indicators are recorded (see Appendix 3).

Recording of patient doses is also useful to assist with optimisation (eg treatment), audit of typical doses against LDoRLs or national clinical guidelines and determination of whether delivered doses are significantly different than intended, as well as for research and service development projects.

All CT and interventional equipment should have a device or features to inform the operator of relevant parameters to assess the patient dose [Regulation 15(5)].

Equipment installed after 6 February 2018 must have the features outlined in Table 10.1 [Regulation 16). Independent checks and verification of key treatment parameters, verification imaging, positional monitoring and *in vivo* dosimetry have a role in ensuring doses are delivered as intended (see Chapter 18 for more details on equipment).

Table 10.1: Requirements for equipment installed after 6 February 2018

Equipment	Required feature
External beam radiotherapy equipment Regulation 16(2)	• Capability to verify key treatment parameters
Planning, guiding and verification equipment Regulation 16(4)	• Capable of informing practitioner of relevant parameters to assess the patient dose
CT and interventional Regulation 16(5)	• Capacity to transfer relevant parameters
Any other equipment producing ionising radiation for medical or non-medical purposes Regulations 16(6)(a) and 16(6)(b)	• Have a device to enable an assessment of patient dose to be made for each exposure • Capacity to transfer this information to the individual's record, where appropriate and practical

10

Patient dose assessment and recording

Imaging doses are typically reported by CT scanners in terms of dose indices such as CTDI or DLP, which should also be included within the patient treatment record to allow retrospective dose calculation if required and inform local dose optimisation. Other forms of concomitant exposures, such as linac-based kV CBCT systems, may not report dose in this way, in which case generic tables of whole-body doses or absorbed doses calculated for each standard protocol may be used as a record of estimated doses. The number of verification imaging exposures is usually recorded in the OMS, so the operator can calculate the accumulative imaging dose at the end of treatment.

Therapy doses are usually simulated within the TPS, considered as part of the optimisation process. A record of this calculation (or any manual alternative) must be included in the OMS as part of the treatment record, along with other key information such as the prescription intent and authorisation of the planned doses. Local clinical protocols should clearly state the expected prescription doses and any objectives for targets or OAR, and these should be readily available to all operators.

Other methods to assess the actual delivered patient dose, such as *in vivo* dosimetry using point dose detectors, imaging panels and dose reconstruction based on equipment log files or on-treatment imaging (eg transit dosimetry), should also be described by employer's procedures. These are usually to verify that doses were given as intended [Regulation 12(2)] but may also be used to aid further optimisation as part of an adaptive radiotherapy protocol (eg to identify and compensate for anatomical changes).

In MRT a proportionate approach to dose assessment, which considers target and OAR, should be taken. MRT is often prescribed as a fixed activity or fixed activity adjusted for body mass or surface area. Clinical protocols should specify a tolerance range on the activity to be administered, which may vary depending on the treatment to be administered. Records of administered activity should be maintained in accordance with the employer's procedure.

Some patients may have theranostic scans to identify suitability of treatment and, in some cases, uptake can be used to optimise the planned administered activity for therapy. Activity administered for these scans, as well as CTDI or DLP for any CT aspects of imaging (SPECT-CT or PET-CT), should be optimised and included within the patient treatment record.

Calculation of delivered doses from the activity administered needs careful consideration. Differences in disease burden and patient uptake result in wide variations in absorbed doses following the administration of the same fixed activity. Accurate determination of absorbed dose following MRT requires quantitative imaging, modelling of the activity distribution over time and calculation of cumulative activity in different regions.

Dosimetry requirements should be specified in local protocols and may vary depending on available resources. Whole-body dosimetry can be conducted using portable or mounted radiation detectors taking a series of external measurements over time. Image-based dosimetry can be conducted to calculate a whole-body dose using a series of whole-body planar scans. In addition, a series of SPECT or PET images can be used to calculate organ and/or lesion dosimetry. To enable internal dosimetry using the series of images; scanner calibrations and quantitative imaging protocols are required with appropriate corrections. The imaging time points should be carefully planned to adequately represent the uptake and the excretion of the tracer. Organs and lesions can be segmented and accumulated activity can be calculated over the scanner time period. This information, along with dose factors, can be used to estimate the absorbed dose to the target or OAR. A range of CE-marked software solutions are available to support these dosimetry calculations, helping to streamline the process and improve consistency in clinical practice.

10

Patient dose assessment and recording

There are many resources available for guidance on MRT dose assessment and recording of appropriate data, such as ARSAC Notes for Guidance,[36] Internal Dosimetry User Group website (www.IDUG.org.uk) and European Association of Nuclear Medicine (EANM) dosimetry guidelines. [69–74.]

Scenario 14

A patient with a neuroendocrine tumour (NET) is undergoing treatment with 177Lu-DOTATATE. Due to impaired kidney function, there is a need to more closely monitor the radiation dose delivered to the kidneys. To support this, three SPECT-CT scans are performed after administration of the first treatment cycle to quantify the activity distribution over time. This allows calculation of the absorbed dose to both the target lesions and organs at risk, including the kidneys. After the third treatment the cumulative kidney dose is calculated to be approaching 27 Gy. In view of the patient's co-morbidities (diabetes and mild renal impairment) it is decided not to proceed with the fourth treatment to avoid exceeding the 27 Gy threshold deemed to be appropriate for this patient.

Determining the absorbed dose to the kidneys enables personalised treatment planning. If the dose to the kidneys is approaching a locally defined critical threshold, adjustments can be made to subsequent treatment cycles, such as reducing the administered activity, extending the interval between treatments or limiting the total number of cycles, to optimise tumour control while minimising the risk of toxicity.

11 Clinical evaluation

Regulation 12(9) requires the employer to ensure that a clinical evaluation of the outcome of all exposures is recorded, including relevant factors associated with the exposure. In practice, clinical evaluation might include the recording and interpretation of therapeutic implications – interpretation of planning or verification images and toxicities in relation to therapeutic exposures. The interpretation of the information resulting from an exposure, including the outcome and implications, should be considered a clinical evaluation. If an exposure is not to be evaluated then it cannot be justified and therefore should not be made.

Clinical evaluation is an operator function. Individuals who carry out clinical evaluation should be adequately trained and entitled, in accordance with the relevant employer's procedure [Schedule 2(b)].

The definition of equipment includes software (including AI-based tools) used to directly assist the trained and entitled operator in carrying out a clinical evaluation. The DHSC guidance describes the software as 'an optional equipment choice which may be used to support clinical evaluation but cannot be used autonomously'. Please see Chapter 18 for further details.[4]

Radiotherapy includes a range of medical exposures and the approach to clinical evaluation for each of these is different. The evaluation should be timely and accurate such that it informs the patient's care. Schedule 2(j) requires an employer's procedure that describes the process for making the clinical evaluation of each type of exposure and recording factors relevant to patient dose, which should be included in the record of clinical evaluation. In practice, these factors are usually retained within the patient medical record or OMS.

Factors to be recorded relevant to the exposure include:

- Dose/fractionation and overall treatment time for external beam and brachytherapy
- Administered activity for MRT
- DLP/CTDi for CT scans
- Local protocol for 2D imaging (number of exposures, kV and mAs should be used to derive local dose estimates for individual protocols or time for cine loops)
- Local protocol for CBCT (number of scans, scan length, kVp or mAs should be used to derive local dose estimates for individual protocols).

No clinical evaluation is required for individuals who are exposed while being a carer or comforter (see Chapter 16).

11

Clinical evaluation

Planning exposures

The clinical evaluation of planning images, such as CT datasets, must be undertaken in accordance with local procedure. Local practice may include where the clinical evaluation is demonstrated by

- The review of the acquired planning images by a member of pretreatment staff for appropriateness and adequacy, prior to transfer of data to the TP
- The review and use of the acquired planning images as part of the treatment plan production process.

The entire CT data set should be used; that is, all slices should be reviewed. The CT data set used must be identifiable in the patient record. The local employer's procedure must stipulate appropriate training to be completed, who is responsible for undertaking the clinical evaluation, where the clinical evaluation is recorded and subsequent audits to be undertaken.

Verification exposures

Medical exposures used for verification of the treatment help to ensure the accuracy of the treatment and will typically be evaluated by the operator prior to delivering the therapeutic dose (eg the radiographer performing image matching). For these exposures, the quality of the image produced is a factor. These clinical evaluations will provide the basis for adjustment or continuation of treatment and may identify the requirement for further medical exposures as per local protocol. The clinical evaluation must be carried out in a timely manner and documented by an entitled operator as per the employer's procedure.

Treatment exposures

DHSC guidance states that evaluation might include the therapeutic implications or 'a clear record that the exposures delivered are consistent with those prescribed, or where these have deviated, the basis for this'.[4] The employer must have a process in place for clinical evaluation of exposures to demonstrate treatment outcomes in terms of acute and late toxicities.

Clinical effects of therapeutic exposures will typically be evaluated through on-treatment and follow-up clinics, including assessment of any toxicity. Regular clinical reviews should be conducted while the patient is on treatment by adequately trained and entitled staff. *Advancing Safer Radiotherapy* provides further guidance on the effective monitoring of early and late effects of radiotherapy and provides recommendations for local and national improvement.[33]

The documentation of the patient review is evidence of clinical evaluation of treatment exposures.

At the conclusion of treatment, an end-of-treatment summary provides a clinical evaluation of the radiotherapy course. At a minimum, the evaluation should record the delivered treatment dose and any reasons why this differs from the prescribed dose. Immediate clinical effects, for example side-effects, should be included as part of the evaluation. For permanent brachytherapy procedures, for example low dose rate prostate brachytherapy, the administered radionuclide and activity at implant should also be recorded.

The end-of-treatment summary should be detailed in local procedures and performed for all radiotherapy exposures. Appendix 7 provides a list of fields for consideration in an end-of-treatment summary letter.

11

Clinical evaluation

Molecular radiotherapy

Scenario 15

A woman has undergone a total thyroidectomy and neck dissection for a papillary thyroid carcinoma with neck node metastases. She receives an ablative 131I administration, 3.7GBq, following rhTSH stimulation. Scintigraphy shows uptake in the neck and thorax, which is shown on SPECT-CT to be due to uptake in the thyroid bed and in two pulmonary metastases. Clinical evaluation in the MDT indicates that she should proceed to a therapy administration of 5.5GBq in due course. The exit scan after the 5.5GBq therapy administration reveals persistent uptake in the lung lesions but resolution of uptake in the neck as a result of the prior ablative administration. Post-treatment monitoring with a CT scan nine months later shows that the pulmonary deposits have cleared and the thyroglobulin has normalised. These evaluations are recorded in the MDT minutes and in the patient record.

Prior to the delivery of MRT, in most cases an assessment of suitability for this treatment with diagnostic imaging will be required. For example, prior to 131I-mIBG therapy for neuroblastoma, or peptide receptor radionuclide therapy for a neuroendocrine cancer, an 123I-mIBG scan with planar scintigraphy and SPECT-CT or somatostatin receptor imaging scan will typically have been performed. The clinical evaluation of these images will ensure that uptake of the tracer by tumour tissue is sufficient, so that treatment with 131I-mIBG or 177Lu- DOTATATE will most likely be effective. Prior quantitative imaging may allow prediction of likely absorbed doses that may be achieved. This will be documented in the formal report of the scan, or in the minutes following review in an MDTM. An exception to this is 131I ablation following surgery for differentiated thyroid cancer, where clinical guidelines specifically advise against pretherapy imaging and it is safe to assume that there will be uptake of the therapeutic radionuclide by residual thyroid tissue or tumour.

Following administration of MRT, qualitative demonstration of the sites of uptake of the radiopharmaceutical should normally be demonstrated on an appropriate scan. This may be omitted where imaging and direct measurements are not possible. Serial imaging may be performed to permit dosimetry of tumour deposits and OAR. Qualitative and quantitative evaluation should be recorded in the report.

Clinical evaluation of outcome will require serial diagnostic imaging to assess disease response. This should be documented in the report and MDT minutes.

12 Identification of the individual to be exposed

IR(ME)R Schedule 2(a) requires the employer to establish 'procedures to identify correctly the individual to be exposed to ionising radiation'. The procedure must specify how and when an individual is to be identified (see Appendix 3).[75]

Correct identification (ID) of the patient is an operator task and must be undertaken prior to any exposure. Operators need to be appropriately entitled for this task. Correct ID of the patient always starts with the referrer as they must supply accurate, up-to-date information to enable the operator to correctly identify the individual to be exposed. Robust employer's procedures should be in place to ensure the individual can be correctly identified in any clinical scenario. These should be supported by fit-for-purpose standardised information technology systems and infrastructure.

The procedure should be positive and active (eg 'What is your name?'). The procedure should state by whom the individual should be identified (eg by the operator carrying out the exposure). This should be consistent across an organisation, where appropriate, and should be developed in line with local governance systems.

For radiotherapy services, the most appropriate and adequate means of positively confirming the ID of the individual is by direct questioning requiring an active response. Three questions should be asked, typically:

- What is your full name?
- What is your date of birth?
- What is your address?

All the responses must match the information provided on the primary source data as specified in the local employer's procedures. This could be the referral for the pretreatment exposures and the prescription for the treatment exposures or the system that holds these. Where photo ID is available this may provide an alternative to one of the above questions or be additional to provide further reassurance to both staff and patient. The photo used should be an appropriate representation of the patient in accordance with local procedures and be available during the ID check procedure. Additional technologies that can assist in the ID process should be reviewed and incorporated where appropriate.

A six-point check is recommended before the initial exposure, including other clinical details (eg site, laterality) that would occur during the pretreatment consultation at the start of the course of treatment. Subsequently patient ID checks could then revert to the standard three points.

The operator undertaking the individual ID check must be identifiable by their signature or electronic password. The employer's procedure should clearly state where the outcome of the patient ID confirmation should be recorded and define the responsibilities of each operator involved. Where possible, the same operator performing the exposure should confirm the individual's ID. However, when there are multiple operators involved in the exposure, the person performing the ID check should clearly communicate and cross-check the individual's ID with the operator undertaking the exposure.

12

Identification of the individual to be exposed

Operators should avoid handovers to colleagues during these essential checks and only do this at the end of each patient fraction. The employer's procedure must describe the process to follow and include what to do where there are discrepancies.

There may be circumstances where it is not possible to implement the three-point ID check. It is important that the employer's procedures identify alternative means of establishing the correct identity of the individual.

Some examples of how this could be achieved are included in Table 12.1. If it is not possible to correctly identify the patient the exposure should not continue.

Table 12.1: Alternative methods of identification

Scenario	Required feature
An individual who is lacking capacity to identify themselves	• Use hospital wristband to confirm ID • Can a relative, carer or staff member confirm the individual's ID?
An individual with sensory impairment (eg deaf or blind)	• Confirm ID using written cards, braille or sign language to assist active process • Could other forms of ID be used (eg photo ID driving licence)?
An individual who speaks an alternative language	• Local policy for the provision of a translation service • Hospitals may require their own interpreter to be present rather than a family member
Paediatric cases	• If the child is unable to answer all of the questions, ID could be completed with a parent, guardian, accompanying nurse or other healthcare professional who knows the child
Patients in theatre or under anaesthesia/ sedation	• Who confirms the ID of the patient?[76] (eg anaesthetist, nurse in charge, surgeon) • Use hospital wristband to confirm ID (eg IORT or SIRT)

Procedures should also indicate how the correct electronic record and accessory equipment are identified at all stages in the process from imaging through to treatment. Additional technologies that can assist in this process should be reviewed and incorporated where appropriate (eg barcoding). Patient safety events have occurred because the wrong electronic data set or accessory equipment has been used to plan or treat a patient.[77]

In MRT, similar principles apply, and procedures should specify how the correct radio-pharmaceutical is identified, including labelling requirements. Further information on AUE is included in Chapter 19.

13 Pregnancy and breastfeeding enquiries

IR(ME)R provides a framework designed to protect individuals from the harmful effects of ionising radiation. This includes the radiation protection of the fetus and those individuals who are breastfeeding.

There is an increased risk of detrimental effects from radiation exposure upon the rapidly growing and dividing cells of an embryo and fetus compared with adults. Employers must have a procedure to establish pregnancy and breastfeeding status of individuals [Schedule 2(c)]. Table 13.1 describes the regulatory requirements relating to pregnancy and breast-feeding and highlights some considerations for inclusion in the employer's procedure.

Table 13.1: Regulatory requirements relating to pregnancy and breastfeeding

Regulation	Required feature
Procedure to establish pregnancy and breastfeeding status Schedule 2(c)	• Specify examinations where pregnancy and breastfeeding (MRT) status enquiries and testing are relevant (see further information in ARSAC notes for guidance for MRT considerations)[36] • Exceptions where pregnancy checking is not required • Specify the cohort of individuals where pregnancy and breastfeeding enquiries are required • Specify the age range for pregnancy enquiries based on local demographics • Process to follow if local decision-making process requires pregnancy testing • Process if more than one operator is involved in an exposure • Process for unconscious, anaesthetised or sedated patients (eg IORT or SIRT • Process for individuals lacking capacity and those with sensory impairment (eg deaf or blind) • Process for how enquiries are recorded • Process for the exposure of pregnant or breastfeeding individuals • Process when pregnancy is disclosed in individuals aged under 16 (including support and safeguarding where appropriate*) • Timing and frequency of establishing pregnancy status • Individuals with irregular menstrual cycles • Inclusion as part of the consent process

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Pregnancy and breastfeeding enquiries

Measures to raise awareness Regulation 6(8)	• Specific and sensitive information to explain the need for pregnancy and breastfeeding status enquiries • Posters and leaflets in waiting areas • Information in appointment letters and leaflets • Adequate training for those involved with patient communication
Justification Regulation 11	• Consider alternative treatments involving less or no ionising radiation • Consider the urgency of the treatment and whether this could be delayed
Optimisation Regulation 12	• Optimised protocols for pregnant individuals • Adequate operator training (how to adjust technique/ protocols) • Usually contraindicated for MRT; guidance for minimising dose to breastfeeding individuals and infants available in ARSAC notes for guidance[36]

* Children under 13 are legally unable to give consent to sexual activity and therefore, if the possibility of pregnancy is reported, follow local safeguarding procedures.[78]

Making pregnancy or breastfeeding enquiries in advance of an exposure is an operator task. It may be considered sufficient to ask prior to initial planning exposure and prior to initial treatment exposure. The referrer is responsible for providing sufficient medical data to enable the practitioner to justify the exposure [Regulation 10(5)]. This data should include the pregnancy and breastfeeding status of the individual. When there is no possibility of pregnancy, local referral guidelines should make it explicit for the referrer to provide the relevant clinical information (such as total abdominal hysterectomy [TAH] or bilateral salpingo-oophorectomy).

Regulation 11(1)(f) requires operators to enquire about pregnancy status where relevant. The process for checking pregnancy and breastfeeding status must be explicitly described in the employer's procedure and any exceptions clearly defined.

The definition of 'where relevant' should be stated clearly in the employer's procedures. For example:

- Enquiries about the possibility of pregnancy may be considered relevant for all individuals with childbearing potential aged between the locally agreed age range.
- It may not be considered relevant to ask an individual if there is any possibility of pregnancy who is known to have had a TAH or who is undergoing medical treatment resulting in infertility or arrested ovulation.
- It may be considered relevant for the operator to ask all individuals who have recently given birth if they are breastfeeding prior to administration of a radioactive substance and to provide them with information and time to discuss the benefits and risks of the procedure.

Wherever possible, any appointment information sent out prior to the medical exposure should explain why the department needs to be aware of the individual's pregnancy or breastfeeding status. The use of waiting room information leaflets and posters highlighting the importance of disclosure of pregnancy, or possible pregnancy or breastfeeding status, is essential [Regulation 6(8)].

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Pregnancy and breastfeeding enquiries

Some individuals may be fearful of initiating conversations about pregnancy for reasons such as abuse, cultural sensitivities and previous experience of gender discrimination. Schedule 3 requires adequate operator training in risk communication. While it is not a requirement of IR(ME)R that referrers are adequately trained, it is considered an important element of patient safety that referrers understand local referral guidelines, appreciate the harmful biological effects of ionising radiation and how this is related to dose and receive practical training in the referral process.

Where a referrer, practitioner or operator is unaware of the possibility of pregnancy or where the individual has not consented to the sharing of their childbearing potential, the individual to be exposed has the sole responsibility for safeguarding the fetus.

Employer's procedure

Establishing pregnancy status can be a sensitive matter, especially, for example, when asking certain individuals: those under the age of 16 years and accompanied by a parent; those known to be transitioning from female to male (trans males); those unwilling or afraid to answer truthfully. The privacy and dignity of the individual should be considered in deciding how these personal conversations occur and with whom the information is shared.

Age range

In many departments, pregnancy enquiries are made for examinations and treatments on individuals of childbearing potential within the age range 12–55 years. However, some departments have liaised with their trust/health board obstetrics team to set an age range that more accurately reflects local patient demographics, for example 10–55 years.

When checking the possibility of pregnancy with individuals under 16 years of age, operators must follow the local safeguarding procedure.

Scenario 16

A 15-year-old patient has been admitted for 131I-mIBG treatment. Prior to administration, pregnancy status must be confirmed. The patient is asked if she has started her periods and the date of her last period. She confirms her last period was more than ten days ago. The patient is also asked, without her parents present, if there is any possibility she could be pregnant and is asked to sign to confirm she is not pregnant. In accordance with the local procedure, a pregnancy test is carried out, because her period started more than ten days ago. This confirms the patient is not pregnant and the exposure may go ahead.

Unconscious, anaesthetised or sedated patients

The employer's procedure must specify whose responsibility it is to confirm pregnancy status prior to the patient being anaesthetised or sedated. This would include patients undergoing IORT or SIRT. NICE clinical guideline *Routine Preoperative Tests for Elective Surgery* recommends enquiring about the possibility of pregnancy, providing information relating to the risks to the fetus, documenting conversations and carrying out a pregnancy test, with consent, if there is any doubt.[79] The procedure may include the use of additional documentation such as the WHO checklist.[76]

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Pregnancy and breastfeeding enquiries

Trans and gender-diverse people

A trans or transgender person is someone whose gender identity differs from the sex they were assigned at birth. Some trans and gender-diverse people who were assigned female at birth may have the potential to become pregnant. The legal process for gender recognition in the UK is set out in the Gender Recognition Act 2004 (GRA 2004).[80]

Consideration should be given to the employer's procedure to ensure it complies with all relevant legislation and reflects the diversity of the gender spectrum in the population when making pregnancy enquiries.[81] The employer's procedure should be in keeping with the wider trust/health board policy on patient dignity and privacy. Tools such as information leaflets, posters and patient questionnaires can be used to facilitate effective communication.

Where a referrer, practitioner or operator is unaware of the possibility of pregnancy or where the individual has not consented to the sharing of their childbearing potential, the individual to be exposed takes responsibility for safeguarding the fetus. It is therefore essential to provide every individual with adequate information relating to the benefits and risks associated with the radiation dose prior to the procedure, as this gives them the opportunity to ask questions and to declare any possibility of pregnancy.

Irregular menstrual cycles

Patients may have irregular menstrual cycles, which may be due to their disease or other illnesses, for example hyperthyroidism or anorexia. In these cases, the traditional ten-day rule and enquiries about menstruation may be ineffective in predicting pregnancy. The employer's procedure may specify that routine pregnancy testing is undertaken in these individuals, following a risk assessment.

Table 13.2 includes additional challenges that operators may encounter when making pregnancy enquiries.

Table 13.2: Considerations when making pregnancy enquiries

Scenario	Required feature
Referrer	• May not have asked the individual prior to referral, or has not provided the information • May not have the individual's consent to share information
Individual	• May not be aware they are pregnant
Specific communication needs	• Individuals lacking capacity • Individuals with sensory impairment (eg deaf or blind) • Individuals who speak an alternative language • Sensitivity for individuals undergoing treatment for cancer that may affect fertility • Sensitivity for gender-diverse individuals
Variable-cycle menstrual periods	• Menstrual cycle may not be regular: • Affected by illness (eg anorexia or hyperthyroidism) • Affected by chemotherapy treatment • Affected by other medical therapies that can disrupt menstruation

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Pregnancy and breastfeeding enquiries

Parent/guardian(s) present	• Individual unwilling or afraid to answer truthfully
Underage sexual activity	• Legal consequences for those under 16 years (include in local safeguarding processes)
Concealed pregnancy	• Vulnerable individuals (eg possibility of sexual abuse)
Religious or cultural beliefs	• Individual unwilling or afraid to answer truthfully (eg unmarried individual)
Trans male or gender-nonconforming individuals	• Use of appropriate language

Breastfeeding

Breastfeeding is completely contraindicated for MRT using radionuclides that are excreted in breast milk.[36]

Patients who are breastfeeding and require MRT need to be advised on the risks to themselves and their baby. If they decide to proceed with treatment, consideration should be given to delaying the treatment until they are no longer breastfeeding and lactation has ceased. Dose to breast tissue from continued lactation should be considered as part of the justification process. Advice from a lactation specialist may be helpful in these cases.

For those patients advised to interrupt breastfeeding, it is imperative they are informed of the duration they have to cease breastfeeding prior to MRT. Guidance is available from ARSAC.[36] Recommendations for specific treatments are also available, such as for thyroid cancer.[82]

Practical application

Following the provision of adequate information, individuals should be asked whether they understood the information and whether they believe they might be pregnant. They are likely to respond with 'No', 'Yes' or 'Not sure' and Table 13.3 includes possible actions to take following each response.

The response to pregnancy enquiries must be documented as evidence that the appropriate questions have been asked. If the individual chooses not to answer questions relating to the possibility of pregnancy, this should be documented and local procedures for unknown pregnancy status followed. The operator should inform the practitioner, who may reconsider justification.

For MRT exposures appropriate counselling in advance of the procedure is of paramount importance to ensure the patient understands the potential risk and rationale for ensuring pregnancy must be excluded. This process should be clearly described in the employer's procedures. The confirmation of menstrual history alone is not considered adequate to exclude pregnancy. Therefore, the appropriate choice of pregnancy test should be described in the employer's procedure along with the information to be recorded in the patient's record. The employer's procedure should also consider reasonable exceptions for some localised therapeutic procedures, for example intra-articular treatments for arthritis.

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Pregnancy and breastfeeding enquiries

Table 13.3: Possible actions following pregnancy enquiries

Response	Possible action
No possibility of pregnancy	• Document and proceed with the exposure
Pregnant	• Inform practitioner of pregnancy status • Confirm if the exposure is still justified and discuss with the practitioner if it can be deferred • Consider deferring the treatment if not urgent • If proceeding, the operator, practitioner and MPE should discuss and decide how the exposure could be further optimised, taking into consideration the potential exposure of the fetus • Involve patient in discussions • Document response and action
Pregnancy cannot be excluded	• If pregnancy cannot be excluded an appropriate choice of pregnancy test should be undertaken as described in the employer's procedure and this information should be recorded in the patient's record • If pregnancy testing is undertaken the employer's procedure should include who does this and the training required; guidance is available on the use of pregnancy testing[79,83,84] • Consider deferring the exposure if uncertainty remains or if the procedure is not urgent

If the possibility of pregnancy is discovered before the exposure takes place, the operator should alert the practitioner, who should reconsider justification of the exposure.

Treating a pregnant patient

Intentional exposure

There are times in external beam radiotherapy practice when a decision is made (through effective justification and patient choice) to deliberately treat a pregnant patient. These occasions are rare and must always be considered on a case-by-case basis. An example of this might be in the case of aggressive disease. However, in all cases there is a requirement to follow employer's procedures. The MPE must be involved in a prior risk assessment of exposures to such individuals. To reduce the potential dose to the fetus, this may involve adaption of the standard planning approach and technique. In addition, there may be a need to consider a multidisciplinary approach in conjunction with an obstetrician and neonatologist.

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Pregnancy and breastfeeding enquiries

Unintentional exposure

If the possibility of pregnancy is discovered after the exposure has been justified or during the course of treatment, the operator should alert the practitioner, who should reconsider justification of the exposure. The MPE should be involved in this process and treatment adapted as appropriate.

All duty holders have a responsibility for the radiation protection of the fetus or breastfeeding individual. Employers should develop procedures to mitigate AUE. If an unintended fetal exposure occurs, this may require notification to the relevant enforcing authority in accordance with published guidance.[85]

Conception following molecular radiotherapy

Male and female patients who wish to conceive following treatment should be advised to avoid getting pregnant for set periods of time as recommended by ARSAC.[36] Where guidance is not available from ARSAC, other recommendations are available, such as for SIRT.[86]

Where patients conceive in the period during which they have been advised not to, consideration should be given to the following in accordance with local procedures:

- Notify the practitioner
- Notify the MPE and request a dose and risk assessment
- Assess impact and plan for ongoing care of patient and fetus where relevant, including consideration of involvement of other expertise, for example obstetrician or radiobiologist
- Practitioner to discuss implications with patient
- Instigate local response procedure
- Consider notification to the relevant enforcing authority where published criteria are met, or shared learning may be beneficial. [85]

14 Communicating benefits and risks and patient information

Communicating the benefits and risks associated with an ionising radiation exposure has always been recognised as a fundamental principle of radiotherapy practice. On a day-to-day basis, IR(ME)R duty holders have conversations with individuals with the intention of improving understanding of the benefits of the exposure and providing information on the associated risks. Schedule 2(i) requires an employer's procedure for providing adequate information relating to the benefits and risks associated with the exposure, formalising this recognised practice. Information should be given, where practicable, to the individual being exposed or their representative prior to the exposure.

Schedule 3 includes the requirement for IR(ME)R duty holders to have adequate training on the benefits and risks of radiation and risk communication. It is recognised that communication of the benefits and risks from radiation exposure can be quite challenging. Individuals and/or their representatives may have difficulty processing information due to an array of emotions, stress, confusion and worry. They may give greater weight to negative information than to positive information being provided. Therefore, it is important to ensure that the benefits of the exposure are clearly described along with the implications of not having the treatment.[87] IR(ME)R duty holders may wish to:

- Reference the justification process
- Emphasise that the exposure is the most appropriate option for their disease
- Explain that the exposure has been tailored to the individual while minimising dose to healthy tissue
- Confirm that the treatment is verified prior to delivery.

In practice, the benefits and risks of all radiotherapy exposures, including planning, verification and treatment, should be covered in one discussion with the individual.

Information may be provided by a combination of IR(ME)R duty holders. The employer's procedures should specify by whom and how this information is delivered to ensure a consistent message is provided across the patient pathway. This information will support the individual being exposed to make an informed decision about the treatment they are being offered.

Written consent is an integral part of the treatment process; this is an established practice.[31,88–90] This addresses the requirement of communicating the benefits and risks of the exposure and should be included in the employer's procedures. Formal consent should be supplemented with written information tailored to the treatment. National site-specific radiotherapy consent forms have been developed by the RCR to support clinicians when consenting patients to radiotherapy.[91]

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Communicating benefits and risks and patient information

The way in which this information is delivered will vary depending on the type of treatment, the individual being exposed, the diverse delivery of service provision, and so on. The information can take various forms, such as posters, leaflets, verbal information or appointment letters, or form part of the written consent. It is important to ensure there is opportunity to ask questions. Within Wales employers should ensure any information is made available in Welsh and English to comply with the requirements of the Welsh Language Act 1993 and the Welsh Language (Wales) Measure 2011.[92,93] Table 14.1 lists examples of different communication methods and things to consider when establishing an employer's procedure.

Table 14.1: Considerations of different methods for communicating benefits and risks

Type of communication	Things to consider
Verbal discussion	• Sufficient time for discussion • Staff training • Use of standard phrases to ensure a consistent message • Patient dignity when choosing the location for discussions • Availability of additional advice (eg MPE)
Written consent	• This occurs following verbal discussion on benefits and risks • Use of national templates where available[91] • Consider access and retention of record • Sharing a copy with the patient
Appointment letter or information leaflet	• Use of standard phrases to ensure consistent message • Invitation to discuss any concerns or request more information • Treatment site-specific information • Restriction periods for MRT
Poster	• Content of information • Placement and visibility of poster • Size and design of poster • Alternative languages • Invitation to discuss any concerns or request more information

Perceptions about radiation can vary widely among individuals, carers and comforters or their representatives. It is the role of the duty holder to assess each individual and tailor the information to their needs. It is important to translate medical terms into understandable concepts and avoid medical jargon, speaking in a concise manner and making sure information given is understood. The individuals should be given the opportunity to ask questions if they have concerns about the information being provided. Effective communication is an integral part of the healthcare professional's role, and dialogue should be tailored to the needs of the individual or their representatives.

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Communicating benefits and risks and patient information

The employer's procedure should be clear as to when to keep a record of any additional information delivered. For example, this could be a verbal conversation with a concerned patient or involvement of the MPE where specific radiation protection information is required based on the individual's circumstances. The procedure should specify where this is recorded, for example on the referral form, the OMS, a consent form or the medical notes. Table 14.2 includes additional situations for inclusion in the employer's procedure.

Table 14.2: Additional situations for inclusion in the employer's procedure

Example situations to be included in the employer's procedure	Things to consider
Paediatric patients	• Information provided to parent/guardian • Language used should be relevant to the age of the patient
Additional advice is required	• Contact details for support (eg MPE or nuclear medicine physician)
Patients lacks capacity	• Information provided to representative
Patients with sensory impairment	• Consider the unique sensory needs, preferences and abilities of individuals • Ensure staff are trained to understand an individual's preferred methods of communication (eg sign language, braille, tactile communication or other suitable alternative)
Patients with neurodiversity	• Consider how to support effective communication with neurodivergent individuals
Individuals who speak alternative languages	• Information leaflets in different languages • How to contact an interpreter
Carers and comforters	• Non-standard situations where additional written information will be required

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Communicating benefits and risks and patient information

Patient information

Regulation 12(6) requires, where appropriate, written instructions and information to be given to patients (or their representatives) who are undergoing treatment with radioactive substances. An employer's procedure on providing this written information is also required [Schedule 2(h)]. A risk assessment will be needed under both IR(ME)R and the IRR to consider the risks to other persons who will be exposed. This should consider typical scenarios and exposures to relatives, members of the public, other medical professionals, care home staff, and so on, and be used to inform the advice and written information given to patients.

The written information should:

- Provide advice on any precautions to observe after the exposure to restrict the dose to other persons that the patient may come into contact with
- Describe the risks from the exposure
- Be provided before the patient leaves the department.

In practice, written information leaflets are often given to patients with their appointment letters including details of how to get further information. Patient-specific instructions or restrictions should be developed in liaison with the MPE and reflect evidence-based practice. The information should be discussed with the individual and issued in writing according to the employer's procedures. Patients should be asked to carry an instruction card while the restrictions are in place, both as a reminder to the patient, but also to alert others such as healthcare professionals who may come into contact with the patient if they become unwell or following a medical emergency.

Guidance is available on patients leaving the department following the administration of sealed or unsealed radioactive substances.[94] An individual risk assessment may be required where patients cannot conform to standard restrictions, and the MPE should be involved in this assessment.

Carers and comforters should be provided with information specifying measures that restrict the dose they receive as much as reasonably possible and below the local dose constraint. Further information on carers and comforters is given in Chapter 16.

15 Children, teenagers and young adults

The IR(ME)R processes of referral, justification, optimisation and clinical evaluation are the same for children and adults, as are the roles and responsibilities of the employer, referrer, practitioner and operator. However, Regulation 12(8)(a) says that the practitioner and operator must pay particular attention to the optimisation of exposures performed on children.

While not stipulated in IR(ME)R, a child is usually defined as a person under the age of 18, or 16 in some jurisdictions.[95,96] Children, teenagers and young adults (defined as ages 0 to 24 years old) are often considered together as a special group of patients in healthcare guidance.[97] However, children under 16 years old have even more specialised requirements in relation to radiotherapy for cancer because of their age. This is for a number of reasons, which practitioners must be aware of:

- Childhood cancer is rare – the incidence for children below the age of 15 is only around 1,600 and for teenagers and young adults aged between 15 and 24 the incidence is 2,100 average cases per year in the UK.[98]
- The majority of childhood cancers do not require radiotherapy, meaning that paediatric radiotherapy comprises less than 1% of all radiotherapy.[98]
- Children usually have a very diverse spectrum of malignancies, with a different range of tumour types compared with adults, meaning that there would be very few patients in each subcategory treated at each department if all departments treated children; patients are referred to a limited number of regional or supraregional centres for photon radiotherapy, two national centres for proton beam radiotherapy and a very limited number of centres nationally for low-volume, high-complexity techniques in children such as brachytherapy, stereotactic radiotherapy and molecular radiotherapy.
- Decision-making by multiprofessional teams with the full range of paediatric oncology expertise is necessary.
- The various normal tissues in children are growing and developing, and so are more susceptible to adverse late effects (including second, radiation-induced, cancers) than in adults.
- Some young children (typically those under 3 or 4 years of age for photon radiotherapy, or 7 or 8 years of age for prolonged treatments such as proton beam radiotherapy, or even older if there are learning or behavioural difficulties) are unable to co-operate with what is required of them and may need daily general anaesthesia for radiotherapy planning and treatment.
- Older children may be anxious and require specialised preparation and extra time to learn what is going to happen, and what is required of them, in order to comply with the requirements of radiotherapy.

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Children, teenagers and young adults

When considering referrals for paediatric radiotherapy, the justification process and protocols used for adults will not be appropriate for children. Specific paediatric referral guidelines must be developed using national and international guidance where available. Very often the most up-to-date and evidence-based guidelines, which represent a consensus of those with most experience in the treatment of particular diseases, are related to international phase III clinical trials. Examples include:

- The International Society of Paediatric Oncology European Neuroblastoma clinical research group (SIOPEN) High-risk Neuroblastoma Study 2.[99]
- The European Paediatric Soft Tissue Sarcoma Study (EpSSG) Frontline and Relapsed Rhabdomyosarcoma Study.[100]
- International Society of Paediatric Oncology Brain Tumours Study Group (SIOPBTSG) HR-MB: An international High-Risk Medulloblastoma trial.[101]

The decision-making about the need (or not) for radiotherapy, and the optimal type of radiotherapy delivery, is not always easy or straightforward. Regulation 11(1)(b) describes how all exposures must be justified to give sufficient net benefit. The potential benefits of radiotherapy treatment, the possibility of alternative treatments that do not use ionising radiation and the associated risks need to be weighed up carefully before a decision can be made [Regulation 11(2)]. The initial forum for these complex discussions is the MDTM at the principal treatment department, but there is a growing number of national advisory panels, mainly run through the Children's Cancer and Leukaemia Group, which offer a greater expertise for certain tumour types such as soft-tissue sarcoma, ependymoma and hypothalamic pituitary axis tumours.

The principles of the planning and delivery of radiotherapy for children are no different to those in adults, but special care is needed.

Before a treatment plan is agreed, the clinical oncologist should meet with the patient and family. Children are not usually able to give valid consent, but they deserve age and developmentally appropriate information about what is proposed, and if their level of understanding is sufficient should be asked to assent to treatment. Alternative treatment options such as radical surgery, and the option of no radiotherapy, should be discussed. Verbal information should be supplemented by written information. This is a specific requirement for the administration of radioactive substances [Regulation 12(6)]. Short-term side-effects and longer-term adverse sequelae, including the risks to fertility and their mitigation and the risks of second malignant neoplasms, need to be discussed. Formal written consent should normally be taken on a separate occasion after the parents/carers have had time to reflect on the information and to ask further questions.

Practitioners should consider the potential for exposures to carers or comforters as part of the consent process. This is only relevant for treatments involving radioactive substances. Further information is given in Chapter 16.

Careful patient positioning, excellent immobilisation and image guidance allow PTV margins to be minimised, thereby reducing the irradiated volume and the dose to OAR. The concomitant dose from image guidance, although significant, should be offset by the increased accuracy of treatment, provided these exposures have been effectively optimised. Additional considerations for optimising paediatric exposures are included in Table 15.1. Early assessment by a play specialist should identify those children for whom general anaesthesia is needed, and those who may be able to co-operate with immobilisation, given time for careful preparation and a developmentally and age-appropriate explanation.

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Children, teenagers and young adults

Table 15.1: Considerations when optimising paediatric exposures

Requirements	Things to consider
Attention to optimisation of paediatric exposures Regulation 12(8)	• Effective and appropriate immobilisation • Appropriate imaging protocols for a range of ages/sizes • Target volumes individually planned • Doses to OAR kept ALARP • Peer review of volume delineation[12] • Delivery appropriately verified • Weight-adjusted administered activity
Adequate training Regulation 17(1)	• Specialist training programmes for operators and practitioners
Co-operation with other specialists involved Regulation 10(6)	• Multiprofessional support and advice • Sharing of relevant information • Multidisciplinary team meetings
Carers and comforters Regulation 6(6)	• Adherence to the dose constraint specified in the employer's procedures (see Chapter 16)

Optimal target volume delineation requires the best possible quality of diagnostic imaging and a high-quality planning scan. As with adults, care must be taken to ensure that the planning scan covers both the intended target and OAR adequately. Intravenous contrast should be used if indicated to show the target and OAR more clearly. Additional data such as operation notes and pathology may also be required.

It is important that target volume delineation, as for other stages of the radiotherapy pathway, is checked for accuracy. Peer review of target volume delineation by another experienced clinician is now regarded as good standard practice, not an optional extra.[12] In clinical trials, there may also be trial-specific peer review as additional QA.

MRT in children needs special facilities with paediatric staffing. The requirements are set out in several authoritative documents.[62,102]

In children with extensive disease whose life expectancy is short, palliative radiotherapy can provide rapid relief of symptoms. As these children are not at risk from late effects, rapid simple treatments, often using single fractions, may be easier and quicker to deliver than complex CT-planned intensity-modulated radiotherapy (IMRT). An example is clinical mark-up with an applied orthovoltage field for a painful bone lesion.

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Children, teenagers and young adults

Paediatric radiotherapy is restricted to a limited number of principal treatment centres. The varied anatomy and pathology of childhood cancers mean that all types of radiotherapy may be required for various indications. Given the very small numbers of patients, and the specialised equipment, facilities and staffing required for some of these techniques, not all will be available at every paediatric radiotherapy centre, and referral to centres of special expertise may be required. *The Good Practice Guide for Paediatric Radiotherapy* sets out ten key principles for the treatment of children with radiotherapy.[62] These essentially echo the requirements of IR(ME)R as applied to children.

Given the specialist knowledge and skills required to treat this patient group, specific training of all operators and practitioners involved in these pathways is essential [Regulation 17(1)]. Consideration should be given to training in paediatric aspects of care, radiotherapy planning and delivery and communication skills for new and existing duty holders (see Chapter 4). Continuing education and training is required to maintain and improve the knowledge base and skills of duty holders [Regulation 6(3)b). Due to the low number of paediatric radiotherapy cases, maintaining competence can be challenging, and therefore CPD and regular review of entitlement (see Chapter 5) are particularly important.

16 Carers and comforters

Carers and comforters are those who are knowingly and willingly exposed to ionising radiation while supporting an individual undergoing an exposure. Where radioactive substances are administered, this will include exposure from support provided after the administration. Typically, carers and comforters will be relatives or friends of the patient exposed who help or give additional care to them. Not all relatives or friends of the patient need to be designated as carers and comforters; many can be considered as members of the public.

The definition of carers and comforters specifies that these individuals are not providing support or care as part of their employment [Regulation 2(1)]. Exposures to professional carers, for example residential care home assistants, should be considered under the IRR.[52]

There is a requirement to have an employer's procedure for the exposure of carers and comforters [Schedule 2(n)]. The employer's procedure should define where individuals may be designated as carers and comforters, include relevant dose constraints and outline the steps to be taken by IR(ME)R duty holders to identify such individuals. There is no lower dose threshold to designate individuals as carers and comforters. All exposures must be justified and authorised on an individual basis. It may be helpful to include guidance on when relatives or friends of the patient do not need to be designated as carers and comforters.

The radiation risk assessment for the treatment should be used to identify standard radiation protection precautions and restrictions, taking into consideration the contact patterns of the individual undergoing the exposure. Where individuals cannot comply with any precautions identified by the radiation risk assessment, due to the level of support and care provided, additional controls will need to be considered as part of the justification process. Under these circumstances individuals may need to be designated as a carer and comforter. This should be documented as part of an individual risk assessment.

It is expected that exposures to carers and comforters will not be justified as part of external beam radiotherapy planning and treatment process and so will not occur. Alternative methods for comfort or immobilisation of patients during these procedures should always be available, for example anaesthesia, sedation or complementary methods such as customised face masks or fiddle blankets.[103, 104]

In MRT and some permanent brachytherapy implant treatments, a person may be designated as a carer and comforter where they attend with a patient and can therefore knowingly and willingly be exposed. The criteria in Table 16.1 should be used to identify such individuals.

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Carers and comforters

Table 16.1: Suggested criteria for carers and comforters

Criteria	Examples
Individuals who provide support and comfort to a patient within a controlled or supervised area (where access is normally restricted, or systems of work are in place to exclude members of the public) Schedule 2(n)	During an exposure: • Being present in the injection room during the administration of radioactive substances • Visiting a patient in a ward treatment room more frequently than usual to provide additional care or support
Individuals who provide support and comfort and are not able or willing to follow the usual instructions regarding radiation protection precautions for patients who have been administered radioactive substances; these should be identified following individual risk assessment Regulations 12(6) and 12(7), Schedule 2(h)	Those who provide additional care: • Help with standard daily tasks including dressing, bathing and toileting • Parents who care for a child after returning home from hospital Those who are not able or willing to follow usual radiation protection precautions: • Children who act in a caring role • The partner of a thyrotoxic patient treated with 131I who is unable to follow standard instructions to sleep apart for a period of time

Scenario 17

A patient receiving radium-223 treatment for metastatic prostate cancer has limited mobility and requires ongoing management of a urinary catheter. Their partner is the primary caregiver and will need to assist with emptying and changing the catheter bag several times a day, as well as helping with personal hygiene and moving between bed and chair.

These tasks involve prolonged and repeated close contact, and there is a potential risk of contamination from handling body fluids. Because this exposure is predictable and cannot be avoided, a formal risk assessment is carried out. This assessment considers typical dose rates from the given tasks, expected care patterns and contamination controls to make an estimate of the dose the partner might receive.

16 Carers and comforters

The employer's procedure may consider scenarios where the justification of the dose to the carer and comforter may require particular attention or additional radiation protection advice from the MPE. Examples include:

- Individuals who are pregnant would not normally be designated as carers and comforters. It is preferable for a non-pregnant relative or friend to offer support instead, but this may not always be practicable. The practitioner may seek the advice of the MPE, who can undertake an appropriate risk assessment and evaluation of potential dose. If the pregnant individual agrees to the exposure, this may be justified by the practitioner. A reduced dose constraint may be appropriate for pregnant carers and comforters.
- Children who act in a caring role would not normally be designated as carers and comforters. Trust/health board procedures for consent should be followed to determine whether children under the age of 18 years (or 16 years in Scotland) can 'knowingly and willingly' consent to an exposure as a carer and comforter. The employer's procedure may require the exposure to these children to be individually justified by the practitioner (rather than including these criteria within authorisation guidelines).

Normally, individuals who do not attend with the patient cannot knowingly and willingly incur an exposure and therefore should be treated as a member of the public. Guidance is available on dose limits and setting dose constraints for members of the public.[105] However, in certain circumstances, it may be possible to get prior written agreement from an individual to be a carer and comforter, without attending with the patient. This type of situation is rare for diagnostic administrations but may be more common for MRT, where close contact restrictions are often given. Where this situation is anticipated, the process should be described in the employer's procedures and appropriately documented.

If a practitioner or authorising operator has followed the employer's procedure and taken reasonable steps prior to the exposure of the patient to identify any potential carers or comforters then no employee has any duties under the regulations, or can be deemed to have been negligent, even if a carer or comforter is identified after the exposure of the patient.

Exposures to carers and comforters require individual justification [Regulation 11(1)(b)]. The justification and authorisation may be carried out by a practitioner; however, where this is not practicable these exposures may be authorised by an entitled operator following authorisation guidelines (see Chapter 7). The trained person who acts as practitioner or authorising operator for an exposure to a carer and comforter should be the person best placed to do so. This might not be the person who initially justifies and authorises the exposure to the patient. For example, the MPE performing the radiation risk assessment may also be entitled as a practitioner to justify the exposures of carers and comforters.

A practitioner justifying exposures to carers and comforters does not need to hold a practitioner licence as required under Regulation 5(1)(b). The practitioner must be a registered healthcare professional and must be appropriately trained and entitled.

Specific matters that must be considered by the practitioner when justifying any exposure (to the individual or to the carer and comforter) are outlined in Table 7.1 [Regulation 11(2)]. Additional considerations must be applied to the justification of exposures to carers or comforters as detailed in Table 7.2 [Regulation 11(3)(b)]. Where authorisation guidelines for carers and comforters are issued, the additional requirements of Regulation 11(3)(b) should be included. The requirements in both Table 7.1 and Table 7.2 must be considered when justifying exposures to carers and comforters.

16 Carers and comforters

The employer's procedure for providing information on the benefits and risks of exposures should include information for carers and comforters [Schedule 2(i)]. Providing adequate information prior to the exposure will allow carers and comforters to understand the benefits and risks involved so that they may knowingly and willingly incur the exposure to themselves. This information should also include advice on precautions or measures to keep the dose to the carer and comforter ALARP.

The way in which information is delivered will vary depending on the type of treatment and can take different forms, including verbal discussions, posters, information leaflets and appointment letters, or form part of verbal consent. Further detail is provided in Chapter 14. Local arrangements may include the use of a form or other documentation to record the information given to or received from the carer and comforter, for example pregnancy status, name and relationship to the individual exposed.

The employer must establish dose constraints for carers and comforters [Regulation 6(5)(d)(ii)]. For most treatments, a dose constraint of 5 mSv can be considered appropriate.[9] The employer's procedure should allow flexibility in setting appropriate dose constraints to encompass the variety of circumstances involving exposure to carers and comforters that may arise, for example where multiple or repeat treatments may be expected and the same individual will act as a carer and comforter more than once. The advice of the MPE should be sought when setting appropriate dose constraints. When individual circumstances require a dose constraint greater than the locally established value, for example relatives or friends caring for patients who require significant amounts of physical care, the rationale for this decision should be documented as specified in the employer's procedure. These exposures must be individually justified by the practitioner, rather than being included as criteria in authorisation guidelines. In these situations, the additional risks to the carer and comforter should be explained fully to ensure that they understand, and additional written information may be given to the carer and comforter.

The employer must establish guidance for the exposure of carers and comforters [Regulation 12(5)]. The MPE should be involved in developing this guidance to provide practical information to keep the exposure to the carer and comforter dose ALARP within the dose constraint. This may include guidance to be given to the carer and comforter about restrictions on close contact time or measures to minimise contamination for patients administered with radioactive substances.

The requirements of Schedule 2(a) to have an employer's procedure to correctly identify the individual to be exposed does not apply to carers and comforters as there is no referrer for an exposure to a carer and comforter and therefore no referral to check ID against. Table 16.2 summarises the requirements for carers and comforters and associated matters to consider.

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Carers and comforters

Table 16.2: Requirements for carers and comforters

Regulatory requirement	Things to consider
Employer's procedure Schedule 2(n)	• Process for designating individuals as carers and comforters • Documentation/records • Involvement of the MPE in setting dose constraints
Employer's procedure Schedule 2(b)	• Identifying appropriate individuals entitled to act as practitioner for justification of exposure to carers and comforters or operators authorising under authorisation guidelines
Individual justification Regulation 11(1)(b)	• Benefits and risks from the exposure to the carer and comforter • Criteria for individual justification by practitioner
Communicating benefits and risks Schedule 2(i)	• Information leaflets for carers and comforters • Non-standard situations where additional written information for carers and comforters is required • Appropriately trained staff to answer any questions the carer or comforter may ask during consent
Establishing dose constraints Regulation 6(5)(d)(ii)	• Dose constraints for standard scenarios and risk assessments • Flexibility to set appropriate dose constraints that cover non-standard circumstances, where an individual risk assessment is required • Involvement of the MPE
Guidance Regulation 12(5)	• Practical information to keep exposure below the dose constraint • Dose monitoring if required as indicated by the risk assessment • Involvement of the MPE

17 Role of the medical physics expert (MPE)

Regulation 14 requires that employers appoint suitable MPEs, describe the role of the MPE and state their required level of involvement in service provision. The level of involvement is commensurate with the hazard and risk associated with each type of practice as follows [Regulation 14(2)]. MPEs must be 'closely involved' in all therapeutic practices, except for standard nuclear medicine therapies, where they must be 'involved'. The MPE should also be 'involved in practices including … high-dose computed tomography', which can be taken to include all planning and verification exposures, for external beam radiotherapy and brachytherapy.

Close involvement in radiotherapy means that one or more MPEs will normally be present on the main site and contactable from all sites during routine working hours, and they may be contactable outside of routine hours for emergency or unusual situations. However, the primary role of the MPE is not troubleshooting or firstline response to issues arising within the radiotherapy department. In many cases, they may be responsible for establishing procedures that address these areas instead of contributing to every underpinning task.

There is guidance available for the employer to establish the required whole-time equivalent staffing level for MPEs based on the services being provided.[106, 107] All radiotherapy departments should have two or more MPEs appointed for sufficient full-time cover, but each of these will take individual responsibility for their role.

Standard and non-standard nuclear medicine therapies should be defined locally and will vary depending on the local expertise and caseload. There is guidance for nuclear medicine therapies available to the employer to support the establishment of the required whole-time equivalent staffing level for MPEs based on the services being provided.[108] The availability and proximity of the MPE should bear a direct relation to the radiation risk involved with the service provision. For example, an MPE for a diverse therapy service should be readily available and normally employed at the site. An MPE for a service providing a single therapy procedure (eg 131I for thyrotoxicosis) could be based off-site. The MPE should be satisfied with the local control arrangements for the sites where they are entitled. Staff need to be aware of how and when to contact their MPE as required.

An MPE is a specific type of operator, but unlike other roles in IR(ME)R (or compared with the radiation protection adviser [RPA] required under IRR), they both advise and act on various aspects listed in Regulation 14(2–3). These can be broadly summarised by four different areas:

- Optimisation (including treatment planning and imaging)
- Equipment management (including commissioning and QA)
- Dosimetry (including calibration and physical dose measurements)
- Regulatory compliance.

The MPE is defined in Regulation 2(1) as those individuals with 'the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to [medical] exposure'. MPEs should be appropriately educated, trained and experienced and hold a certificate issued by RPA2000 as nationally assessed, in accordance with DHSC frameworks.[39, 40] They should normally be a clinical scientist with appropriate post-registration experience, specialising in radiotherapy physics.

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Role of the medical physics expert (MPE)

Local appointment should be in accordance with individual job descriptions and subject to periodic review, for example during annual appraisals, taking into account CPD and maintenance of HCPC registration and MPE certificate of competence.[39] MPEs should be entitled for their scope of practice as an operator in accordance with the employer's procedures. Scope of practice should be agreed with the employer; this task is usually delegated to the head of radiotherapy physics or head of medical physics. The appointment of the MPE should distinguish between external beam therapy, sealed sources and unsealed sources, since practice can vary greatly between these areas. MPEs must use their professional judgement and not act or advise in areas where they are not competent, or outside their scope of practice.

Areas for MPE involvement are summarised in Table 17.1, but this list is not exhaustive nor exclusive to one individual.

Table 17.1: Examples of the roles of an MPE

Area	Example roles
Equipment procurement and commissioning	• Advise and input on selection of all radiotherapy equipment • Preparation of technical specifications and installation design
Equipment management	• Acceptance testing • Commissioning of new equipment or techniques • Selection of appropriate test equipment • Definition and management of QA of equipment, including corrective action to be taken when tolerances are exceeded • Update and management of equipment inventory • Managing equipment faults • Technical management of clinical computing software and systems, in collaboration with hospital IT staff
Dosimetry	• Absolute dosimetry of treatment equipment, including definitive calibration, management and calibration of dosimetry equipment • Physical measurements for the evaluation of dose delivered, including pretreatment (phantom-based measurements) and on-treatment (*in vivo* dosimetry)
Optimisation	• Contribute to the development and review of imaging protocols and DoRLs for treatment planning and verification imaging • Dose audits • Contribute to preparation of protocols for standard treatments, including checking and peer review, and be responsible for provision of beam data for planning calculations • Consult on the suitability of immobilisation, imaging and treatment techniques, in particular for customised or non-standard situations • Consult on, and be responsible for, the suitability and accuracy of methods used to calculate dose distributions in radiotherapy procedures • Advise on the optimisation of complex treatment plans and dose assessment of any changes during treatment • Contribute to audit of new or modified techniques, including risk assessments to inform practice change

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Role of the medical physics expert (MPE)

General protection and regulation compliance	• Consult on strategic planning issues that involve possible changes to the radiotherapy service, including decisions on therapy equipment, modalities or techniques • Contribute to the analysis of events involving, or potentially involving, AUE, including reconstruction of dose delivered • Contribute to the training of practitioners, operators and other staff in relevant aspects of radiation protection, in collaboration with MPEs from other sections as appropriate • Advise their employer on compliance with IR(ME)R, in collaboration with MPEs from other sections as appropriate • Advise and contribute, as appropriate, to all aspects of the radiation safety of radiotherapy equipment, in collaboration with the RPA, radiation protection supervisors (RPS) and radiation waste adviser (RWA) • Consult on the radiation safety aspects of research projects, in collaboration with the RPA and other MPEs as appropriate • Contribute to the safe and secure management of sealed sources in brachytherapy, including supporting employer licence applications, in collaboration with MPEs from other sections as appropriate Several areas in the above list will benefit from collaboration with MPEs in other sections of medical physics, such as diagnostic radiology and radiation safety. This includes image optimisation, training and advice on compliance with regulations.

Regulation 14(4) requires the MPE to liaise with the RPA and RWA as appropriate, even though these roles have no statutory responsibility under IR(ME)R. Areas of overlap may include:

- Surveillance of installations
- Selection of equipment for radiation protection measurements
- Training of staff and research exposures (as described in Table 17.1).

It is likely there will be some overlap between these two roles, but for radiotherapy they will usually be different people, and procedures should clearly state which role is responsible for which aspect. In general, any advice relating to radiation protection of staff, trainees or the public is the responsibility of the RPA, and any advice or activity relating to protection of the patient and carers and comforters (see Chapter 16) is the responsibility of the MPE.

18 Equipment and quality assurance

Regulation 15 of IR(ME)R sets out the requirements in relation to all equipment regardless of when it was installed or brought into clinical service. Regulation 16 of IR(ME)R sets out additional requirements for all equipment installed after 6 February 2018.

Definition of equipment under IR(ME)R

Within IR(ME)R 'equipment' is defined as equipment (including software) that:

- 'Delivers' ionising radiation to a person undergoing an exposure;
- 'Directly controls or influences' the extent of the exposure and hence the dose delivered; or
- Directly assists an operator in carrying out a clinical evaluation [Regulation 2].[4]

Any software tools (including AI-based tools) used to directly assist the trained and entitled operator in the clinical evaluation should be included in the equipment inventory. Examples of such equipment are provided below. These tools do not replace the operator's role or responsibility and may not be used autonomously.

Examples of equipment delivering ionising radiation include:

- CT simulator
- Linear accelerator
- In-room X-ray imaging (eg CBCT system attached to linear accelerator)
- Kilovoltage treatment unit (eg superficial, orthovoltage, intraoperative)
- High dose rate (HDR) brachytherapy unit
- SPECT-CT and PET-CT scanners if used for direct planning.

Examples of equipment (including software) that influences the dose delivered include:

- Treatment planning systems, including any software that provides the primary calculation of monitor units required or dose delivered
- Oncology management systems, including any software that tracks the total dose delivered as fractionated treatment
- Contrast injectors, which trigger the scan acquisition automatically
- Respiratory gating systems, which automatically start and stop the beam
- Ultrasound-guided systems for positioning of brachytherapy seeds
- Automated contouring or segmentation software, including those based on generative AI algorithms[11]
- MRI scanners if used directly for treatment planning without a corresponding planning CT scan, or are used to produce 'synthetic CT' images
- Dose calibrators, calculation software and any imaging equipment (eg gamma cameras) used in MRT to determine the dose delivered
- Dose rate monitors used for patient monitoring before leaving the hospital.

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Equipment and quality assurance

Examples of equipment (including software) that assists clinical evaluation include:

- Image-processing software that assists the operator in evaluating the image quality or usefulness for treatment planning; note there may be some overlap with tools that also influence the dose delivered, such as artifact reduction algorithms
- Software that automates collection of patient-reported outcomes (PROMs) or toxicities, which inform follow-up appointments or other evaluation of treatment efficacy
- Software for image matching as part of radiotherapy treatment verification
- Software used to estimate doses to OAR for post-exposure review in MRT.

Local procedures and workflow will determine which equipment meets the IR(ME)R definition and should be reviewed regularly.

The definition of equipment extends to all new or second-hand units, as well as any loan equipment, while used for medical exposures within the employer's control. Clear procedures on co-operation between employers and responsibilities should be established where equipment is used by one employer in the facility of another (eg off-site IORT or brachytherapy).

Equipment and the employer's responsibilities

Regulation 15 defines the general duties of the employer with respect to equipment. These are summarised in Table 18.1 and discussed in more detail below.

Equipment QA refers to the planned system required to ensure that equipment performs satisfactorily and in compliance with the regulations. This includes the actions necessary to ensure that the QA system is working as it should, such as audit. Quality control (QC) is one of the component parts of a QA programme and refers to operations carried out to improve equipment quality such as testing, monitoring, evaluation and maintenance.

Table 18.1: Employer's duties regarding equipment

Equipment duties on the employer	Things to consider
Implement and maintain a QA programme Regulation 15(1)(a)	Include in the employer's procedure the arrangement for QA including: • Types of tests • Frequency • Who is responsible for carrying out each test and handover arrangements • MPE involvement
Keep an up-to-date inventory of equipment (including relevant software) Regulation 15(1)(b)	• Include software and all ancillary equipment that can directly influence the exposure or assist with clinical evaluation • Include all ancillary equipment • Remove any equipment no longer in use
Carry out testing of equipment prior to use for any medical purpose Regulation 15(3)(a)	• Programme for acceptance testing

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Carry out regular performance testing Regulation 15(3)(b)	• Agreed programme for local routine QA • Daily/weekly/monthly/quarterly/annual testing
Carry out testing following any maintenance that may affect the equipment's performance Regulation 15(3)(c)	• Carry out testing following any maintenance that may affect the equipment's performance • Regulation 15(3)(c)
Specify acceptable equipment performance criteria, including ensuring measures are in place to improve equipment performance where it is inadequate or specifying corrective action to be taken in the case of defective equipment Regulations 15(6)(a), 15(6)(b) and 15(6)(c)	• Record QA results • Define baselines, tolerance and action levels • Procedure to take equipment out of service • MPE involvement • Risk register • Image optimisation process
Equipment must have a device capable of automatically controlling the radiation dose rate, such as an image intensifier Regulation 15(4)	• MPE involvement in specification for any fluoroscopy equipment (eg SIRT)
Equipment must have the capability to provide an indication of the radiation dose delivered to the patient during any procedure Regulation 15(5)	• MPE involvement in specification for any interventional radiology (eg SIRT) and CT equipment

Equipment inventory

The employer must maintain an up-to-date inventory of hardware and software equipment, including ancillary devices that can directly control or influence the exposure or assist in clinical evaluation, that can be given to the enforcing authority upon request [Regulation 15(1)(b)].

As a minimum, for each item of equipment the inventory must contain [Regulation 15(2)]:

- Manufacturer
- Model number
- Serial number (or alternative unique identifier)
- Year of manufacture
- Year of installation.

For any software, the inventory must contain:

- Software company
- Brand name
- Current version
- Year of original installation
- Year of current version installation

The equipment inventory should be reviewed on a regular basis and updated when new equipment is installed or when equipment is no longer in use.

For the majority of equipment, creating and maintaining such an inventory is straightforward. Imaging systems attached to linear accelerators may have their own serial number and, if so,

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should be listed separately. It may be the case that items defined as equipment under IR(ME)R are not held within the radiotherapy department, for example an MR scanner used for MR-only planning. Such items should also be included in the inventory and an additional column for item location added.

Software that is part of the equipment itself and/or used to support image processing prior to clinical evaluation does not need to be included separately in an inventory under this definition (eg 4DCT reconstruction or metal artifact reduction applied on the scanner itself).

Electrometer–ion chamber combinations and associated dosimetry equipment used to determine machine output and definitive calibration could also be considered as influencing the dose delivered to an individual during an exposure, but it is recommended that such devices are not categorised as equipment according to the IR(ME)R definition. They are used to define the performance of equipment and measure the dose delivered, and as such appropriate maintenance and QA of such devices is the responsibility of the MPE.

An exception can be made for dose calibrators used for directly measuring the activity to be administered to an individual in MRT. Dose calibrators can be used not only for confirming the activity of capsules ordered for therapeutic treatments, such as 131I capsules, but also for ensuring the appropriate activity is drawn up for injecting radioisotopes, such as 223Ra, used for the treatment of bone metastases. Consequently, such equipment should be included in the inventory.

Equipment performance and QA

It is the employer's responsibility to implement and maintain a QA programme for all equipment as defined in Regulation 15(1)(a). Such QA programmes must enable the dose from an exposure or the administered activity to be determined. These are minimum requirements and the majority of QA programmes will enable a much more comprehensive assessment of equipment function and performance.

The MPE must contribute to defining programmes of QA as indicated in Regulations 14(2)(d) and 14(3)(b). The regulations use standard definitions for QA and QC to ensure that equipment QA is implemented and maintained. The practitioner and operator have a duty to comply with the QA procedures [Regulation 10(1)]. The operator has a specific responsibility to consider QA when ensuring that exposures are ALARP [Regulation 12(3)(a)]. The specific requirements for equipment QA will depend on the type of equipment and local agreements regarding who will cover which specific tests. The advice of an MPE should be sought when reviewing results of such QA testing. It is essential that an MPE is consulted when formulating and maintaining a QA programme. Table 18.2 includes some items to consider in developing a QA programme. Further detail on the role of the MPE is included in Chapter 17.

The QA programme should also include procedures for recording:

- Faults on equipment
- Whether the equipment was removed or partially restricted from clinical use
- Any corrective actions necessary
- Any tests made before return to clinical use.

IR(ME)R discusses equipment performance in terms of:

- Testing of equipment before first use
- Regular performance testing of equipment
- Performance testing following maintenance that may have affected the equipment's performance.

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Table 18.2: Considerations in the development of a QA programme

Programme	Things to consider
When to test?	• Frequency of standard testing • Following an external service engineer's visit • Following in-house repair or component change
Who will test?	• Radiographer (eg daily tests) • Medical physics (eg clinical scientist, technologist)
Prior to testing	• Equipment handover (eg AXREM form)[109] • Engineer's report • Check equipment log for known issues • MPE advice/oversight
During testing	• Specific tests for each equipment type • How to set up specific tests, including distances, exposure parameters, position of phantoms • Recording of results • Availability of tolerances • Record of assessment of results against tolerances
After testing	• Reporting of any issues (eg by discussion and/or in writing to MPE, dosimetry clinical scientist, linac engineer, lead radiographer) • Details of actions required (eg speak to MPE, repeat test, remove equipment from service) • Record of any actions taken and return to service • Equipment handover (eg AXREM form)
Review and improvement	• Periodic review of results to show performance over time • Training records of those performing QA
Risk management	• Identification, risk assessment and subsequent management of inadequate or defective equipment • Systems in place to identify and mitigate risk, for example management of QC results or analysis of patient safety events • Access control to equipment, including management of remote access • Systems implemented to ensure proportionate response dependent on level of access and potential risk

The QA programme should also include software. Software that forms part of hardware equipment, such as linac, management systems that handle patient data and interface with hardware, along with third-party packages that also contribute to the radiotherapy pathway can have a critical impact on the safety and accuracy of exposures delivered.

In developing a QA programme for software particular consideration should be given to:

- Risk-based testing, in accordance with the potential impact of any malfunction or miscalculation
- Testing of both individual software functions and the interfaces with other systems, for example using end-to-end workflow tests
- Validation using clinically realistic data and usage patterns, and against standard datasets or processes to ensure consistency of outputs, along with any reference data

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- Data integrity and security within the software and transfers to and from other systems
- Strict control of any updates or modifications, with testing commensurate with the level of change being made, and fully documented
- Fault logs, known issues and the process for clinical user feedback, support and training
- Governance and compliance with local hospital and national policies, such as information governance and information security
- Back-up of data and continuity plans if software is unavailable.

Testing of equipment prior to first use

The MPE must contribute to the technical specification of new equipment and installation design [Regulation 14(3)(d)]. In practice, the MPE should actively participate in equipment appraisal and support the development of relevant business cases for the acquisition of new equipment. Thereafter, it is the responsibility of the employer to undertake acceptance testing. Regulation 14(3)(b) states that the MPE must contribute to the acceptance testing of equipment, and therefore acceptance testing and commissioning of equipment before first clinical use should be undertaken by appropriately trained and competent operators who have been entitled to undertake such tasks.

Acceptance testing is often undertaken in conjunction with the service engineers employed by the manufacturer to install the equipment as it is used to determine whether the equipment meets the manufacturer's predefined performance criteria. Subsequent to acceptance testing it is usual for further commissioning checks to be undertaken, which will often set baselines against which future performance can be assessed.

Regular performance testing

A programme of QA for equipment will include all QC checks necessary to ensure the equipment meets acceptable performance criteria. Published guidance such as IPEM reports can be used as a reference for QC of radiotherapy equipment and provides frequencies and action limits to apply during performance testing.[110–112]

The employer must specify acceptable performance criteria. Baseline values are usually ascertained at commissioning, with appropriate tolerances defined within the QC procedures. The employer must also specify the corrective action necessary if equipment is shown not to meet the predefined performance criteria during testing. This must include the option of taking equipment out of service [Regulation 15(6)]. Any corrective action must be undertaken as soon as possible. Obsolete or superseded equipment should be decommissioned, as it is unlikely to keep doses ALARP and consistent with the therapeutic purpose. Regular monitoring of equipment performance and trend analysis can be used to help predict when adjustments need to be made prior to values falling outside of set limits. Published guidance is only a guide and the frequency of checks can be based on trend analysis and local risk assessment as appropriate.

Performance testing following maintenance

Maintenance and repair of equipment can affect performance. It is essential that appropriate checks are undertaken prior to returning equipment to clinical use. This ensures baseline values continue to be met and, if not, that adjustments are made to ensure equipment continues to perform as expected. Manufacturers often define the checks to be undertaken after repair and, as a minimum, local procedures should reflect these.

All practical aspects or procedures that may affect the dose delivered to a patient should be undertaken only by appropriately trained and competent operators. Training records and scope of practice should reflect which individuals are appropriately trained, competent

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and entitled to undertake performance testing and QC procedures. These should include who is responsible for returning equipment to clinical use after any maintenance, repair or adjustment that may affect performance. External service engineers would not normally be considered operators, since appropriate tests are performed by local staff before release for clinical use. Robust procedures for handover should be established between external engineers and local clinical scientists or technologist staff, for example use of AXREM form.[109]

Employer's procedures Schedule 2(d)

A procedure must be in place to ensure that QA programmes relating to equipment are followed. A regular retrospective audit of equipment QC can be used to determine whether routine performance testing was undertaken following predefined timescales and that out-of-tolerance measurements were investigated and acted upon as per local procedures. This should also include the procedures followed after maintenance and repair. Further detail on requirements surrounding written procedures is included in Chapter 3.

Equipment located away from the radiotherapy department

Any equipment that can influence the dose delivered to a patient during an exposure falls within the equipment definition in IR(ME)R and consequently the same general duties of the employer apply. It is acknowledged that some equipment falling into this category (MRI scanners, PET-CT) may not be located within a radiotherapy department; however, it should be ascertained that appropriate performance testing is being undertaken to meet the requirements of IR(ME)R.

Equipment features

Fluoroscopy and CT

The use of fluoroscopy in radiotherapy is limited, but any equipment must have systems to keep doses ALARP, such as automatic dose rate (exposure) control or an image intensifier [Regulation 15(4)]. Special attention should be given to the accuracy of dose estimates and there should be systems of work to optimise exposures (eg to minimise exposure time) where these are used (eg estimation of breathing motion).

The requirements of Regulation 15(5) relate specifically to CT scanners. The scanner must have a means of informing the practitioner of relevant parameters with which to assess patient dose. Essentially the CTDIvol and DLP along with overall scan length should be available upon completion of any scan. It is recommended that these parameters are recorded within the patient record so they can be easily viewed if required.

Equipment installed after 6 February 2018

Equipment wholly installed since the regulations became active has additional requirements for dose information recording and transfer [Regulation 16]. This does not apply to new components on existing equipment. In general, all radiation equipment must be able to record relevant parameters for assessment of dose, at least for retrospective calculation. For volumetric imaging, this may include parameters such as CTDIvol and DLP as described above. For planar imaging it may include kV, mAs, field size, and so on. In addition, the number of exposures (not just reconstructed images) must be recorded, to allow cumulative estimates of imaging dose to be calculated.

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All devices must have the capacity to transfer this information to the patient's treatment record, where appropriate [Regulation 16(6)(b)]. In practice, this transfer may be automated to the OMS, but manual transfer may also occur, if appropriate safeguards against manual transcription errors are in place. In general, such dose information should be transferred to the main patient treatment record wherever practical, to avoid reliance on separate or legacy systems.

Megavoltage external beam radiotherapy equipment (eg linacs) must be able to verify key treatment parameters [Regulation 16(2)]. In practice, this would be the record and verify system, working as part of the OMS, which either spans several pieces of equipment (eg a fleet of linacs) or monitors a single piece of radiation equipment (eg as the record and verify system does on some individual treatment devices). For standalone units especially, appropriate resilience should be established for back-up and retrospective access to key parameters as may be required.

Equipment management

An MDT approach to equipment management is essential. Table 18.3 describes matters to consider throughout the life cycle of medical radiological equipment.

Table 18.3: Matters to consider throughout equipment life cycle

Stages of equipment life cycle	Things to consider
Selection of equipment	Inclusion of the MPE within the MDT involved in: • Choosing the most appropriate equipment to meet the service requirements • Procurement phase of equipment selection • Assessment of dose optimisation features on imaging equipment
Installation	• Testing of equipment before it is first used • Setting up protocols and optimisation of doses • Working with application specialists, clinical leads and other relevant staff
Critical examinations	• Following initial installation • Following major service or maintenance where there may be radiation protection implications
Acceptance testing	• Testing of equipment before clinical use [Regulation 15(3)(a)]
QA programme	• Testing of equipment performance at specified intervals and after any major maintenance procedure • Extent of the programme will depend on the nature and range of equipment in use • Definition of acceptable performance criteria [Regulation 15(6)(b)]
Maintenance	• Performance testing on a regular basis [Regulation 15(3)(b)] • Employer should establish clear procedures for acceptance of equipment back into clinical use following service or maintenance [Regulation 15(3)(c)]
Inadequate or defective equipment	• Assessment for aging equipment • Escalation process for dealing with inadequate or defective equipment [Regulation 15(6)(a) and (c)]

19 Accidental or unintended exposures (AUE)

Accidental or unintended exposures

Regulation 2 defines the terms accidental exposure and unintended exposure. These apply to radiation incidents that involve equipment, procedural or systematic failure. The regulations require the employer to provide a system for analysis, recording, reporting and ensuring appropriate action is taken in relation to AUE [Regulation 8(3)]. The MPE must contribute to this incident analysis system [Regulation 14(3)(f)].

IR(ME)R differentiates between significant accidental or unintended exposures (SAUE) and clinically significant accidental or unintended exposures (CSAUE). Regulation 8(1) requires the referrer, practitioner and individual exposed or their representative to be informed of a CSAUE. The employer must notify the relevant enforcing authority when either a SAUE or CSAUE occurs in accordance with the relevant enforcing authorities' joint guidance.

Significant accidental or unintended exposures

These exposures are significantly greater than what was intended as part of any exposure or significantly lower than was intended as part of a therapy exposure. The relevant enforcing authority's joint guidance details notification thresholds and requirements for SAUE.[85]

The practitioner and MDT should review each SAUE case individually to determine if the clinical impact of the event meets the definition of CSAUE and take appropriate action.

Clinically significant accidental or unintended exposures

These AUE have a clinically significant impact on the individual exposed.

A CSAUE is defined as an accidental or unintended exposure that results in moderate harm to the patient or a significant risk to the patient's tumour control, normal tissue toxicity or quality of life.

When deciding if something is CSAUE a risk-based assessment with due consideration to the dosimetric information provided by the MPE, patient factors, potential toxicity and tumour control factors should be completed. Examples of CSAUE in radiotherapy and MRT are provided in Table 19.1.

The Learn from Patient Safety Events (LFPSE) service defines moderate harm, giving consideration to both physical and psychological harm. The medical opinion of the multiprofessional healthcare team should be taken into account when considering harm that may be physical or psychological.[113] The harm caused may be acute, and require a change in management or additional interventions, or the CSAUE may cause a significant increase in long-term risks.

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Local procedures should detail who is responsible for determining whether an AUE is clinically significant, for example the clinical oncologist responsible for the management of the patient's care. In rare circumstances, the clinical significance might not be identified until sometime after the exposure when it affects the individual's quality of life, for example unexpected progression of disease or side-effects at the wrong anatomical site.

Examples of CSAUE are described in Table 19.1.

Table 19.1: Examples of CSAUE

These situations will often be SAUE, but the practitioner and MDT should review each case individually to determine if the AUE is clinically significant
1. The treatment dose is planned and delivered to the incorrect anatomical volume resulting in significant risk to the patient's tumour control and subsequent success of treatment
2. When a higher treatment dose is delivered unintentionally to surrounding OAR, resulting in a measurable effect on the patient's normal tissue toxicity requiring medical intervention
3. When the treatment dose is suboptimally planned and delivered resulting in a measurable effect on the patient's quality of life
4. When a lower treatment dose is delivered unintentionally to the target volume resulting in a suboptimal outcome for the patient
5. When there is an unintended clinical impact or compromise in the effectiveness of treatment, regardless of dose due to incorrect scheduling of treatment
6. Extravasation of radiopharmaceuticals resulting in skin doses above 5 Gy[54]
7. Failure to follow thyroid-blocking procedure resulting in an unintended dose to the thyroid of more than 50 mGy from administered radiopharmaceuticals[36]

It is important to note that justified exposures, where it is known in advance (or becomes apparent during treatment) that an adverse outcome may occur, are not CSAUE under IR(ME)R. These exposures may result in:

- Expected side-effects that the patient was consented for
- Expected side-effects where the patient was not reconsented following a change to the plan
- Some unexpected side-effects that the patient was not consented for.

As there is wide variability in individual patient response to radiotherapy, it can be initially difficult to distinguish between patients experiencing an unusual reaction from a CSAUE. In all cases, an immediate local investigation should be carried out to ensure the patient is appropriately supported and it is confirmed that all exposures were delivered as intended. Investigation of severe or rare adverse clinical effects may facilitate the identification of suboptimal planning or delivery of radiotherapy, including patient preparation and immobilisation.[33]

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Dose estimate

For any radiation incident an estimate of the dose received by the target volume, OAR and normal tissues must be calculated and recorded by the MPE for comparison with the planned dose. This dose information can then be used to:

- Determine whether there is scope for compensation or correction during the remainder of the treatment course
- Determine the dose consequence of any geographical miss
- Determine whether the incident meets the notification criteria for a SAUE
- Inform the discussion around whether the incident is clinically significant (CSAUE).

For circumstances where a dose correction is possible within the fractions remaining, consideration needs to be given to the time required for the replan to be completed and whether this requires a gap or delay in the treatment course.

In MRT, dose estimates can be completed based on locally available dosimetry techniques, administered activity, SmPC, verification imaging and peer-reviewed publications.

Employer's procedure for communicating CSAUE

Regulation 8(1) requires that the employer's procedure [Schedule 2(I)] must set out the process for informing the referrer, practitioner and individual involved or their representative when a CSAUE has occurred and provide information on the outcome of the investigation of the incident.

It is important to recognise that individuals may react differently to being informed about an AUE. This can be influenced by many factors including, for example, age, mental health and the magnitude of the exposure.

Further detailed guidance is available on dealing with the consequences of significant radiotherapy events and offering support to the patient.[33] Employers may need to consider appropriate investigation training of duty holders, and it may be helpful to develop supporting documents to aid this process. Further details on communicating risk information can be found in Chapter 14.

Good practice will include the requirements of Schedule 2(I) within a comprehensive radiotherapy event (RTE) management procedure. Table 19.2 includes things to consider for inclusion within a comprehensive procedure.

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Table 19.2: Considerations for local radiotherapy event (RTE) management procedure

Area	Things to consider
Preliminary investigation process	• Immediate action to protect patient safety • Action to ensure the event is not repeated (eg equipment taken out of service) • How duty holders identify and record patient safety events • Mechanism for local reporting • Specify information required to determine what happened, where and when it happened, contributory factors and how the event was detected • Identify staff members responsible for the internal escalation process (eg practitioner, team leader or head of service) • Involvement of the MPE (eg estimation of overexposure) • External notification thresholds and timescales (eg SAUE guidance,[85] CSAUE definition) • Identify responsible person for notifying the relevant enforcing authority (where required)
Detailed investigation process	• Appropriate event response undertaken by MDT • Report on what actually happened and compare with what should have happened • Analysis and identification of system wide contributory factors • Record of event response (eg investigation) • Appropriate action taken to prevent or minimise risk of similar event recurring • MPE to calculate accidental or unintended dose delivered and compare to planned dose • Establish if any others may be similarly affected • Trend analysis and comparison with other similar events[77, 114] • Systems analysis, effectiveness of current safety actions • Disseminate learning • Assessment of resultant harm, and associated risk to patient in consideration of CSAUE
CSAUE	• Involvement of the practitioner, MPE and local care team • Identify responsible person for informing the individual exposed or their representative, usually the clinical oncologist or nuclear medicine physician • Inform the individual exposed/representative, referrer and practitioner • Record of information provided and discussions held • Record of a decision not to inform the individual exposed, including detailed justification

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Analysis of events	• Coding and classification of patient safety events[115,116] • Systematic analysis of patient safety events, to facilitate continuing learning and improvement [3,114,115] • Identification of thematic trends, including areas that require review and improvement, informing changes to practice • Record actions required to address areas for improvement • Monitor the progress of required actions and assess effectiveness post implementation (eg did the action taken result in an improvement?) • Communicate and share learning themes to all stakeholders within the organisation, as well as regionally and nationally as appropriate • Utilise output of analysis to inform local study of risk of AUE

Some radiation incidents may require a retrospective review of previously treated patients to determine whether a similar event has occurred. A clinical decision needs to be made as to whether their subsequent management needs to be altered.

Notification to the relevant enforcing authority

Regulation 8(4) sets out the process the employer must follow when it is believed that a CSAUE or SAUE has or may have occurred:

- Carry out a preliminary investigation
- Immediately notify the relevant enforcing authority in accordance with SAUE guidance[85]
- Carry out a detailed investigation including assessing the potential dose received
- Notify the relevant enforcing authority of the outcome and corrective actions.

Guidance is available from the enforcing authorities on situations where a SAUE should be notified to them along with appropriate timescales for notification.[85] CSAUE should be identified utilising the definition provided within this guidance and notified to the enforcing authority. Notifications to the relevant enforcing authority should include contact details of an individual who can provide further information as required. Notifications should not include information that could identify the patient or staff involved.

IR(ME)R is enforced by different organisations across the UK:

- In England, the enforcing authority is Care Quality Commission (CQC)
- In Northern Ireland, The Regulation and Quality Improvement Authority (RQIA) is the regulator for inspection and enforcement of IR(ME)R (Northern Ireland) 2018
- In Scotland, Scottish Ministers delegate the powers to inspect for compliance with IR(ME)R to Healthcare Improvement Scotland (HIS)
- In Wales, Welsh Ministers ensure compliance with IR(ME)R through an operationally independent part of the Welsh Government, Healthcare Inspectorate Wales (HIW).

Where the incident cause relates to equipment failures, other enforcing authorities should be notified; for example, the Medicines and Healthcare products Regulatory Agency (MHRA) in England, Wales and Northern Ireland, and the Incident Reporting and Investigation Centre (IRIC) Scotland.

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The process of investigation should be standardised.[117] It is important that everyone involved in the identification, reporting, analysis, taking action and notification of AUE understands the value of the process and actively contributes so that learning can be shared and patient safety is improved.[118]

All radiotherapy providers should have documentation in place that clearly sets out local reporting criteria for AUE and demonstrates due consideration to the SAUE guidance and Table 19.1.[85] It is strongly recommended, in cases where there is some ambiguity about an event meeting the local criteria, that a notification is made to the relevant enforcing authority.

Systems for recording analyses of events

Regulation 8(3) requires the employer to put in place systems for recording analyses of events, proportional to the risks involved. Such systems must address both actual and potential AUE. In accordance with Regulation 8(3) radiotherapy departments have well-established local event learning systems in place for the recording, investigation, analysis, taking appropriate action and learning from patient safety events.

The fundamental role of reporting and learning systems is to enhance patient safety by learning from failures of the healthcare system.[119] Events may arise from multiple, interacting components of a system. The investigation should therefore adopt a system-based approach, to ensure all contributory factors are identified and appropriate action is taken.

Although each event is unique, there are likely to be similarities and patterns that may go unnoticed if radiation incidents are not reported and analysed. There is emerging evidence that organisations with a higher rate of reporting have a stronger safety culture.[33] All radiotherapy departments should have clear guidelines on patient safety event management and actions to be taken when patient safety events occur. Guidance for coding and classification of patient safety events is available.[115,116]

Documentation relating to patient safety events should be retained in line with relevant guidance.[120] Clinical departments should ensure all staff have access to learning from patient safety events including the safety actions required to mitigate the recurrence of these events.

Participation in the national voluntary event learning system is indicative of an open and transparent safety culture.[33,77,114–116] This provides opportunities to learn from a greater pool of data and facilitates local benchmarking of events with the national picture to support a reduction in the magnitude and probability of these radiation incidents. Learning from radiation incidents should be local, national and international.

Outputs from patient safety event analysis should be used to inform risk assessments in thematic areas identified in the analysis as part of a study of the risk of AUE.

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Study of risk

Regulation 8(2) requires the employer to implement a QA programme of radiotherapeutic practices that includes a study of the risk of AUE.

This is in addition to QA programmes relating to written procedures and written protocols and equipment, as required in Regulations 6(5)(b) and 15(1)(a).

The study of risk needs to be clearly directed at AUE. A working example from a radiotherapy department is provided in Appendix 8.

The European Commission (EC) advocates proactive risk assessment as an effective tool of risk management in radiotherapy to identify preventive measures.[17] The EC provides a useful definition for risk management as referring to:

all the various organizational structures and processes that are designed to improve safety and prevent or reduce risks, or that limit the consequences of risks (ie, all risk preventive measures). Risk management is, therefore, part of the overall quality management program.

A study of risk is a proactive process that helps organisations to understand the range of risks (both internal and external) that they face, their capacity to control those risks, the likelihood (probability) of the risk occurring and their potential impact. This involves quantifying risks and using judgement, assessing and balancing risks and benefits and weighing these against cost.[17]

Different methods of risk assessment are available, but none of these alone can achieve all the aims described above. Rather, a combination of methods is needed to perform a complete evaluation. This will also be influenced by the other safety actions in place within the service. To understand how these risk assessment methods are applied in radiotherapy, besides general concepts of risk (eg hazard, failure mode, barrier), the EC guidelines describe the different steps involved, including important concepts such as likelihood and severity scales and a criticality matrix. For risk assessment to be effective, it is imperative to ensure risk mitigation has been designed in to processes and that this is clearly documented. Consideration should also be given to integrating risk mitigations with other business processes as appropriate. This might include capital spend, change management, training and commissioning.

Risk assessment should include both proactive risk assessment and reactive analysis of events. Proactive risk assessment is well suited to the study of possible organisational, equipment, procedural or systematic failures, and is useful for identifying safety actions that can be implemented to limit the consequences of events.[17] Reactive analysis of events focuses on the study of a specific event, and involves the investigation of contributory factors, identification of safety actions that failed and the corrective measures required. This type of analysis should be used to update proactive risk assessments.[17]

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A recognised risk assessment approach should be used and adapted as required. Nominally this would include one of the following:

- Risk matrix
- Failure mode, effects and criticality analysis
- Fault tree analysis
- Preliminary hazard and risk analysis
- Event tree analysis.

Radiotherapy departments will have local analysis from their local event learning system, as required under Regulation 8(3), to focus and prioritise the risk assessment.

Consideration should also be given to using published data to inform the local risk assessment.[77,114,121–125]

The timing and frequency of completion of risk assessment should also be considered, particularly in the following situations:

- Prior to introducing a significant change to practice
- Prior to introducing a new technique or technology
- Following a SAUE (reported locally or nationally) or a series of similar patient safety radiotherapy events.

An MDT should be involved in the organisation of a risk assessment programme. This team should have appropriate training in the methods of risk assessment used and knowledge of the relevant work area.

Outcomes of the risk assessment should be fed back to the wider staff group and be actioned to inform practice. Employers should consider regular safety learning events that cover a standard agenda, including proactive and reactive risk assessments and learning from patient safety events. The risk assessment programme needs to be encouraged, resourced and supported by management as part of an effective safety culture.

Reducing the probability and magnitude of AUE

Staff are more likely to report patient safety events where there is an open, learning culture and where the clear aim of reporting is to learn and to improve patient safety.[33] An increase in the reporting of events is not necessarily an indication of worsening patient safety; it may indicate an increasing level of awareness of safety issues among healthcare professionals and an evolving reporting culture within an organisation.

Employers should share the outcomes of analyses with all relevant staff and apply lessons learned to take appropriate action, so that these events may be mitigated in future.

Schedule 2(k) requires the employer to have an employer's procedure to identify how the probability and magnitude of AUE are reduced. Table 19.3 provides examples for consideration of areas to include in this employer's procedure.

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Table 19.3: Employer's procedure to reduce the probability and magnitude of AUE

Area	Things to consider
Governance	• Establishment of radiation protection committees or similar • Clear arrangements for co-operation between employers • Consideration of professional and national guidance to inform service delivery • Independent and peer review • Requirement for professional registration of staff and codes of conduct
Optimisation	• Use of DoRLs for CT planning exposures and CBCT where appropriate [63–65] • Adoption of national IGRT protocols[126] • Adoption of national treatment prescriptions where appropriate[56] • Delivery of therapeutic exposures appropriately verified • MPE involvement • See Table 8.2
Communication	• Effective communication with the patient to improve co-operation during exposures • Culture of MDT working • Communication with all duty holders to share learning themes and promote compliance with the employer's procedures
Audit	• Participation in IPEM regional dosimetry audits and surveys[127] • Clinical audit to include all parts of the clinical pathway • IR(ME)R compliance audit to monitor compliance with employer's procedures
QA programmes	• Robust QA programme for documentation and equipment • Procedures and protocols are documented, regularly reviewed and monitored through a robust programme of internal and external audit
Training programmes	• Training for all duty holders with supporting evidence of competence once training is complete • Continuing education and training, for example prior to the clinical implementation of new techniques or technologies
Entitlement	• Effective entitlement process with up-to-date scope of practice for individual duty holders
Patient safety event analysis	• Analysis of trends to identify areas for improvement and drive continuing improvement • Local and national event learning systems implemented to facilitate shared learning, locally, regionally and nationally

20 Nuclear medicine licensing

Regulation 5 requires employers and practitioners who administer radioactive substances to hold a valid licence. Each employer licence is specific to the site where administrations will take place and lists the authorised procedures (examinations) that may be carried out for diagnostic, therapeutic and research purposes. Each practitioner licence lists the authorised procedures that may be justified by the named licence holder for diagnostic, therapeutic and research purposes.

Applications for licences are assessed by ARSAC and issued by the appropriate licensing authority.[36,37] Regulation 2 defines who the appropriate licensing authority is for employers and practitioners in England, Scotland, Wales and Northern Ireland. The licensing authorities are listed in Table 20.1.

Table 20.1: Licensing authorities in the UK

Country	Employer licensing authority	Practitioner licensing authority
England	Secretary of State	Secretary of State
Scotland	Scottish Ministers	Secretary of State
Wales	Welsh Ministers	Secretary of State
Northern Ireland	Department of Health	Department of Health

Employer licences

Employer licences are required at each hospital site where radiopharmaceuticals will be administered. Employers are responsible for the safe administration of radioactive substances and hold additional responsibilities, such as establishing appropriate procedures, protocols and QA systems [Regulation 6), entitlement of duty holders [Schedule 2(b)], management of equipment and providing adequate facilities for administration [Regulation 15]. Licence applications require the employer to demonstrate compliance with IR(ME)R.

Practitioner licences

Practitioner licences are required in addition to the employer licence. The practitioner licence details the procedure codes that the practitioner may justify and may be considered as the practitioner's scope of practice. Individuals who hold a practitioner licence must be entitled as practitioners in accordance with the employer's procedure. Where practitioners work at multiple sites or for multiple employers their local entitlement should be clear.

Guidance on application of authorisation guidelines is included in Chapter 7.

There is no reciprocal recognition of practitioner licences between Great Britain and Northern Ireland. If a practitioner moves between Great Britain and Northern Ireland they will need to apply for a new licence. Within Great Britain, practitioners may move between England, Wales and Scotland and practise under the same licence.

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Nuclear medicine licensing

In order to carry out a procedure (examination), the relevant procedure code must be included on both the employer and practitioner licences for the same purpose. Detailed guidance on how to apply for a licence is provided by ARSAC.[36]

Scenario 18

A practitioner holds a licence for the full range of diagnostic nuclear medicine procedure codes listed in the ARSAC Notes for Guidance and some unsealed source therapy procedures codes. The licensed practitioner is entitled by an employer at two hospital sites within a trust, one of which has inpatient treatment facilities. At the site with the inpatient treatment facilities, the practitioner is entitled to justify the full scope of procedure codes on their licence, but at the other site they are only entitled to justify the diagnostic procedure codes listed on their licence.

Licensing for research involving radioactive substances

Research involving the administration of sealed or unsealed radioactive substances requires approval from ARSAC [Regulation 11(1)(d)]. Details of the approval process are provided in Chapter 21. ARSAC research approvals specify the approved procedure codes for each trial. To take part in a research trial, the approved procedure codes for the study need to be held on both the employer and practitioner licences for the purposes of research. If these procedure codes are not held, the licences should be amended appropriately following ARSAC guidance.[36]

Administration of other prescription-only medicines (POM) as part of a nuclear medicine procedure

Regulation 240 of the Human Medicines Regulations 2012 was amended when the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 came into force.[128,129] This allows IR(ME)R operators to administer other medicines as part of a nuclear medicine procedure, for example reno-protective amino acid infusions as part of a 177Lu DOTATATE treatment. Certain conditions need to be met prior to administration of the medicine:

- The POM is not a product subject to special medical prescription
- The administration of the POM is included in the protocol
- The exposure is justified by a practitioner who holds a licence for the administration of the radioactive substance
- The exposure is authorised by a practitioner or an operator following authorisation guidelines
- The POM is administered by an operator in accordance with the protocol.

This regulation permits operators who are not registered healthcare professionals to administer POMs, but each operator must also be trained and entitled to do this according to the employer's procedure.

21 Research exposures

IR(ME)R contains a number of research-specific requirements that must be met in addition to those that apply to all medical exposures. Table 21.1 lists the requirements and things to consider when carrying out research.

Table 21.1: List of requirements under the regulations for research

Regulation	Requirements
Licensing Regulations 5 and 11(1)(a)	• Appropriate employer and practitioner licences must be in place prior to commencing research trials (or programmes) involving the administration of radioactive substances
Regulation 6(5)(d)(i)	The employer must establish: • Dose constraints for exposures involving individuals taking part in biomedical and medical research trials where no direct medical benefit is expected from the exposure
Justification Regulation11(1)(d)	• All research trials must be approved by a recognised research ethics committee (REC) before commencing • All research trials involving the administration of radioactive substances must be approved by ARSAC
Optimisation Regulation 12(4)	The employer's procedures must ensure: • Consent to take part in the research trial is given • Individuals or their representatives are told in advance about the risks of the exposures • Established dose constraints are adhered to • Individual target levels of dose are planned for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a medical benefit

The employer is also required to have in place an employer's procedure regarding exposures involving ionising radiation for research purposes [Schedule 2(g)]. Table 21.2 includes considerations for inclusion in this employer's procedure and gives some examples of how the written procedure could describe how they may be addressed in practice.

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Table 21.2: Considerations for inclusion in employer's procedure on research

Requirement	Things to include in the employer's procedure
Approval by a recognised REC and ARSAC (administration of radioactive substances)	• Brief description of how the local research and development approval process ensures that REC and, where applicable, ARSAC approvals are in place
Practitioner and employer licences	• Process to ensure that appropriate licences are held to cover all administrations of radioactive substances required by the research trial
Consent process	• Clear description of the research consent process • Consider the process for individuals who are unable to consent (eg paediatric patients)
Individuals informed in advance about the risks of the exposure	• Participant information sheet (PIS) • Radiation risk information within the PIS should follow guidance from the Health Research Authority (HRA)[128,129]
Dose constraints	• Description of how a dose constraint is set for each research trial and how centrally reviewed data are used to inform local dose constraints • Local dose constraints should be optimised and reasonable variations in local practice (eg available equipment) taken into consideration • Process to ensure dose constraints are adhered to
Dose targets	• Description of how individual dose target levels are set • Description of how delivered doses are recorded and monitored

Central review and approval for research

The HRA has produced guidance to aid research trial sponsors in determining if the exposures within a trial are research exposures.[129] ARSAC has produced guidance to describe when ARSAC research approval must be obtained.[130] Ethics committee and ARSAC approvals are two separate activities and do not automatically mean that all the research exposures included in the study have been justified and authorised on an individual level.

Ethics committee approval

Before any research involving exposures to ionising radiation can go ahead, the research trial must be approved by a REC. This ensures the ethical merit of the trial has been evaluated by a group of individuals with the appropriate knowledge and skills. Further detailed guidance is available from the HRA on how to apply for REC approval.[129]

ARSAC approval

Research involving the administration of sealed or unsealed radioactive substances will require approval from ARSAC. Research sponsors are responsible for obtaining ARSAC research approval. Detailed information on this process can be found on the ARSAC website.[130] ARSAC research approvals will specify the radiopharmaceutical and its use.

Considerations for research trial initiation at site

A local governance and oversight process is required so that the employer can assure itself it can meet the requirements of IR(ME)R for research. This should include a proportionate

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Research exposures

review of the research trial requirements to ensure that the site can safely deliver the associated exposures.

Licensing for the administration of radioactive substances

Appropriate employer and practitioner licences are required prior to commencing a research study involving the administration of radioactive substances. The procedure codes approved for the study need to be held on both the employer and practitioner licences for the purposes of research. If these procedures are not held, the licences should be amended appropriately following ARSAC guidance.[132]

Referral

Consideration must be given to who is acting as the referrer for these exposures and how the referral for exposure is evidenced. The individual acting as the referrer must be a registered healthcare professional who is entitled as a referrer. The wider requirements related to referrals also apply to research exposure. The employer's procedure should also describe how referrers must identify research exposures to enable staff to recognise the referral as research. This in turn enables the practitioner and the operator to select the correct protocol for the research study.

Justification

Justification and authorisation are required for each individual exposure. The practitioner may take into account the ethical considerations regarding the study population for the individual patient, but the individual characteristics of each patient, including contraindications, must also be considered. This needs to be recorded as part of the process of authorisation.

Where the exposures in the whole study have been approved by the REC and ARSAC (where appropriate), and contain information approved by a lead MPE and clinical radiation expert, a practitioner under IR(ME)R should justify and authorise each exposure. Consideration should be given to local processes for how this can be achieved.

Practical considerations

IR(ME)R requires employer's procedures to provide safeguards for medical and biomedical research trials. It is important that local departmental staff can identify those exposures that are for research purposes. This can be achieved in several ways, such as by selecting a status icon or alert on the OMS or using a specific study code on the referral. These processes should be described in the employer's procedures. A list of current trials should be made available to staff within the local department.

A specific protocol is required for each research trial and these should be readily available to staff. This should include:

- The dose constraint or dose target for relevant research exposures as appropriate
- The number, type and timings of required exposures
- The imaging protocol.

It may be helpful to consider having a local research file, network drive or specified intranet location where all documentation can be easily accessed. Other useful information should be stored including contact details of the local research team members, the principal investigator, the expected end date of the research study, a copy of all relevant approvals, including those from the REC and ARSAC, and relevant employer and practitioner licence information.

Regular communication between the local department and the local research team is encouraged.

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Appendix 1. Glossary

Term	Definition
Adequate training	Training that satisfies the requirements of IR(ME)R Schedule 3 (see Chapter 4).
Authorisation	The documentation confirming that the process of justification has occurred (see Chapter 7).
Brachytherapy	Sealed source therapy. The use of radioactive implants such as seeds, pellets, wires or plates that are put near or inside the disease.
Carer and comforter	Individuals who are knowingly and willingly exposed to ionising radiation while supporting a patient undergoing an exposure. Where radioactive substances are administered, this will include exposure from support provided after the administration. Typically, carers and comforters will be relatives or friends of the patient. Nurses, healthcare assistants or prison officers accompanying a patient are not carers and comforters (see Chapter 16).
Clinical audit	A systematic examination or review of procedures that seeks to improve the quality and outcome of patient care through structured review, whereby practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated, and the application of new standards if necessary. To ensure ongoing quality improvement this is usually a continual process (see Chapter 3).
Clinical evaluation	An interpretation of the outcome and implications of the information resulting from a medical exposure. Radiotherapy includes a range of medical exposures and the approach to clinical evaluation for each of these is different (see Chapter 11).
Clinical scientist	In this document, clinical scientists are those individuals trained in medical physics and registered with the Health and Care Professions Council.
Clinical oncologist	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 or equivalent approved training.
Clinically significant accidental or unintended exposure (CSAUE)	A CSAUE is one that has resulted or is expected to result in moderate harm to the patient or a significant risk to the patient's tumour control, normal tissue toxicity or quality of life. Effects may be acute, and require a change in management or additional interventions, or they may cause a significant increase in long-term risks (see Chapter 19).
Concomitant exposures	Planning and verification exposures.
Continuing professional development (CPD)	The planned acquisition of knowledge, experience and skills and the development of personal qualities throughout the working life of an individual (see Chapter 4).
Dose constraint	Part of the optimisation process, a dose constraint is a restriction set on a prospective dose from a radiation source (see Chapters 16 and 21).
Dose target	Target levels of doses planned for research exposures where direct patient benefit is expected (eg experimental therapeutic practices) (see Chapter 21).
Employer	Any 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, those exposures described in Regulation 3 or practical aspects, at a given radiological installation (see Chapter 2).

Entitlement	An employer responsibility, this is the process of verifying training and competencies and defining the tasks, or scope of practice, that duty holders can undertake (see Chapter 5).
External beam radiotherapy	Radiation source is placed at a distance from the patient – includes teletherapy (linac-based delivery), superficial, orthovoltage and X-ray based IORT.
Justification	This is an intellectual process of weighing up the potential benefit of a medical exposure against the detriment for that individual. It must include consideration of techniques that involve less or no ionising radiation (see Chapter 7).
Licensing authority	For practitioner licences, in Great Britain, the Secretary of State; in Northern Ireland, the Department of Health. For employer licences, in England, the Secretary of State; in Scotland, the Scottish Ministers; in Wales, the Welsh Ministers; in Northern Ireland, the Department of Health (see Chapter 20).
Medical exposure	An exposure coming within paragraphs (a) to (e) of Regulation 3. Three types of medical exposures are utilised within radiotherapy practice: patients as part of their medical diagnosis or treatment; individuals participating in research programmes; carers and comforters (see Chapter 1).
Medical physics expert (MPE)	An individual or a group of individuals having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to exposure, whose competence in this respect is recognised by the Secretary of State in Great Britain or the Department of Health in Northern Ireland (see Chapter 17).
Molecular radiotherapy (MRT)	Unsealed source therapy. The administration of a radiopharmaceutical in the treatment of disease.
NHS trust/health board	A division within the NHS generally serving a geographical area. In Scotland and Wales these are referred to as health boards. Where the term 'trust' has been used in this document, this applies equally to health boards and independent healthcare providers.
Nuclear medicine physician	A specialist doctor who has completed the Royal College of Physicians (RCP) Nuclear Medicine Training Programme.
Operator	Any person who is entitled, in accordance with the employer's procedures, to carry out the practical aspects of a medical exposure (see Chapter 2).
Optimisation	This is the process by which individual doses are kept as low as reasonably practicable, in keeping with the therapeutic purpose (see Chapter 8).
Patient safety event (PSE)	A PSE encompasses patient safety incidents and good care. A patient safety incident is where something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm. Good care means events that can be learned from.
Policy	A high-level statement governing the conduct of activities in an organisation. Policies outline what will be done with minimal details as to how this will be achieved (see Chapter 3).
Practitioner	A registered healthcare professional who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures (see Chapter 2).
Procedure	A detailed description of the control mechanisms for a process indicating detailed management arrangements and responsibilities. Employer's procedures must be complied with by practitioners and operators (see Chapter 3).

Protocol	Guidance on the detail of each medical exposure based on a consensus of opinion. They should be specific to each examination and machine. They must be written down and their status clear. Protocols should allow latitude for professional judgement (see Chapter 3).
Quality assurance (QA)	All those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with generally applicable standards, and quality control is a part of QA (see Chapter 3).
Quality control (QC)	The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured and controlled (see Chapter 18).
Radiographer	An allied health professional who is registered with the Health and Care Professions Council. Therapeutic radiographers are responsible for the planning and delivery of accurate radiotherapy treatments using a wide range of technical equipment.
Radiotherapy	The treatment of disease, especially cancer, using ionising radiation. This includes external beam radiotherapy, brachytherapy and MRT.
Radiotherapy event	A nonconformance where there is an unintended divergence between a radiotherapy treatment delivered or a radiotherapy process followed and that defined as correct by local protocol. This includes events that lead to radiation incidents that might be minor, SAUE, CSAUE or good catches (see Chapter 19).
Referrer	A registered healthcare professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposures. In Northern Ireland, this also includes medical practitioners registered with the Medical Council of Ireland (see Chapter 2).
Registered healthcare professional	A person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002. Examples of regulated healthcare professionals are doctors, dentists, nurses, midwives, radiographers, clinical scientists, physiotherapists, chiropractors. Examples of professional body regulators are General Medical Council, General Dental Council, Health and Care Professions Council.
Relevant enforcing authority	Enforcing authorities for IR(ME)R: • England – Care Quality Commission • Northern Ireland – The Regulation and Quality Improvement Authority • Scotland – Healthcare Improvement Scotland • Wales – Healthcare Inspectorate Wales
Scope of practice	Describes a range of skills and tasks based on professional registration, education, training, knowledge and experience.
Signature	For the purposes of this document, signature is defined as either handwritten in the paper environment or an electronic signature in the paperless environment (see Chapter 2).
Significant accidental or unintended exposure (SAUE)	An exposure that was significantly greater than that intended. The regulations require that SAUE are notified to the relevant enforcing authorities (see Chapter 19).
Supervision	The action or process of watching and directing what someone does or how something is done and being able to change this when required. Under IR(ME)R the supervisor will be an entitled duty holder and as such retains responsibility for the task they are supervising (see Chapter 4).

Appendix 2. Abbreviations

Abbreviation	Definition
AHCS	Academy for Healthcare Science
AI	Artificial intelligence
ALARP	As low as reasonably practicable
AP	Assistant practitioners
ARSAC	Administration of Radioactive Substances Advisory Committee
AUE	Accidental or unintended exposures
AXREM	Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care
BSSD	Basic Safety Standards Directive
CBCT	Cone beam computed tomography
CESR	Certificate of Eligibility of Specialist Registration
CCT	Certificate of Completion of Specialist Training
CoR	College of Radiographers
CPD	Continuing professional development
CSAUE	Clinically significant accidental or unintended exposure
CTDI	Computed tomography dose index
CTV	Clinical target volume
DHSC	Department of Health and Social Care
DLP	Dose length product
DoRLs	Dose reference levels
DRLs	Diagnostic reference levels
EANM	European Association of Nuclear Medicine
EC	European Commission
EPR	Electronic patient record
FRCR	Fellowship of The Royal College of Radiologists
GDPR	General Data Protection Regulation
GRA	Gender Recognition Act
GMC	General Medical Council
GTV	Gross tumour volume
HCPC	Health and Care Professions Council
HRA	Health Research Authority
ID	Identification
ICRP	International Commission on Radiological Protection
IGRT	Image-guided radiotherapy
IMP	Investigational medicinal product
IMRT	Intensity-modulated radiotherapy
IORT	Intraoperative radiation therapy
IRIC	Incident Reporting and Investigation Centre
IPEM	Institute of Physics and Engineering in Medicine
LFPSE	Learn from Patient Safety Events

MDT	Multidisciplinary team
MDTM	Multidisciplinary team meeting
MEC	Medical exposures committee
MHRA	Medicines and Healthcare products Regulatory Agency
MPE	Medical physics expert
MRI	Magnetic resonance imaging
MRT	Molecular radiotherapy
NET	Neuroendocrine tumours
NICE	National Institute for Health and Care Excellence
OAR	Organs at risk
OMS	Oncology management system
PACS	Picture archiving and communication system
PET/CT	Positron emission tomography-computed tomography
PIS	Participant information sheet
POM	Prescription-only medicine
PPE	Personal protective equipment
PTV	Planning target volume
QA	Quality assurance
QC	Quality control
QMS	Quality management system
RCR	The Royal College of Radiologists
REC	Research ethics committee
RIS	Radiological information system
RPA/ RPS/ RWA	Radiation protection adviser/ radiation protection supervisor/ radioactive waste adviser
RPC	Radiation protection committee
RTE	Radiotherapy event
SAUE	Significant accidental or unintended exposure
SBRT	Stereotactic body radiotherapy
SCoR	Society and College of Radiographers
SIRT	Selective internal radiotherapy
SmPC	Summary of product characteristics
SPECT	Single photon emission computed tomography
SUV	Standardised uptake values
TAH	Total abdominal hysterectomy
TPS	Treatment planning system
TRPD	Total research protocol dose
VMAT	Volumetric modulated arc therapy
WHO	World Health Organization

Appendix 3. Considerations for inclusion in the employer's procedures

Regulation 6(1) requires the employer to have in place written procedures as specified in Schedule 2. Table A3 lists the employer's procedures required and provides examples of what the employer may wish to consider for inclusion, but this list is not exhaustive. The employer may provide additional Schedule 2 procedures than the minimum required by IR(ME)R. Further information can be found in the main body of this guidance, which should be read in conjunction with this appendix.

Table A3: Things to consider including in employer's procedures

a) Identification of individual to be exposed

- Who is responsible for carrying out ID checks? How are they identified?
- When does the ID check happen?
- What questions will the operator ask to identify the individual?
- What if there is more than one operator involved?
- What primary source data is used to check ID?
- What is the process if there is a discrepancy with the individual's demographics?
- What is the process where verbal communication is not possible? (eg language barriers, age, mental capacity, unconscious, sedated)
- How is the ID-checking process recorded?
- How are the correct dataset and ancillary equipment identified?
- How is the correct radiopharmaceutical identified?

b) Identification of individuals entitled as duty holders

- How are duty holders made aware of their responsibilities under IR(ME)R?
- How is the task of entitlement delegated by the employer?
- How is entitlement authorised and who can entitle duty holders?
- How are training and competencies assessed and signed off?
- How often are training, competencies and entitlement reviewed and by whom?
- How do staff demonstrate their entitlement and scope of practice?
- Clarify who holds the training records
- Include who is responsible for auditing and reviewing entitlement/scope of practice

c) Enquiries of individuals to establish pregnancy and breastfeeding status

- Who is responsible for checking pregnancy and breastfeeding status?
- What is the age range for enquiries?
- When is pregnancy checking required? (describe any exceptions)
- When and where does the pregnancy check happen?
- How are responses recorded?
- What are the measures to raise awareness? (eg posters, appointment letters)
- What is the process when more than one operator is involved in an exposure?
- What is the process where verbal communication is not possible? (eg language barriers, age, mental capacity, unconscious, sedated)
- What is the process if an individual is unsure or says that they are pregnant?
- What is the process to follow if pregnancy testing is part of establishing pregnancy status?
- What is the process for the exposure of pregnant individuals?
- Include contact details and safeguarding procedures

d) QA programme for written procedures, protocols and equipment

Written procedures and protocols

- What should be included in the standard template? (eg version number, author, authorised by, issue date, review date)
- Define the document control authorisation process
- How often and when are procedures/protocols reviewed?
- Who is responsible for the review process and accuracy of content?
- How do different staff groups access procedures and protocols?
- How are changes communicated to all relevant staff?

Equipment

- What equipment will be tested and how often? (eg daily, monthly, annually)
- Who will carry out the tests?
- How and where are results recorded?
- What happens when results are out of tolerance?
- Who acts on results? (eg who contacts MPE, manufacturers)
- How is equipment handed over and how is this documented?
- How are equipment issues reported and to whom?
- How is training provided to those carrying out equipment QA?
- How is equipment returned to service?
- What is the process for corrective actions when defective or inadequate equipment is identified?

e) Assessment of patient dose and administered activity

- What dose information needs to be recorded and where?
- Who is responsible for recording this information?
- What dose indicators for each modality will be recorded?
- Describe methods used to verify the delivered dose (eg the use of *in vivo* dosimetry or transit dosimetry)

f) Use and review of DRLs and DoRLs

- What DRLs or DoRLs are in place?
- Where can they be found? (eg displayed in control areas or included within local imaging protocol)
- Is there MDT involvement in the development of DRLs or DoRLs?
- How often are they reviewed and by whom?
- What actions are taken by the staff and the employer if they are being consistently exceeded?
- Consider DRLs for hybrid imaging used pre/post-therapy scans in MRT

g) Research exposures

- What is the process for local research and development approval?
- What is the process to ensure appropriate licences for the administration of radioactive substances are in place?
- Is there a link to the PIS?
- How are dose constraints set?
- How are dose targets set?
- How is adherence to dose constraints ensured?
- How do duty holders identify research exposures?
- How are duty holders made aware of research protocols?

h) Written information for nuclear medicine

- How is the advice provided on precautions to observe after the exposure?
- How is the individual informed of the risks from the exposure?
- When should the information be provided to the patient/individual? (eg at the booking stage, prior to leaving the department)
- Where can additional information be found?
- What information is provided to the parent/guardian/representative?
- Contact details for support (eg MPE or nuclear medicine physician)
- Do information leaflets need to be in different languages or is an interpreter required?
- Non-standard situations where additional written information will be required

i) Communication of benefits and risks of exposures

- What information will be given to the individual?
- Who provides this information?
- How will the information be provided? (eg as part of consent, verbal, information leaflets or posters)
- Where will the information be provided?
- How will staff access support for additional information if required? (eg MPE or practitioner)
- Who will provide training to staff giving this information?
- How do the method and level of communication reflect the risk?
- What is the process where verbal communication is not possible? (eg language barriers, age, mental capacity, unconscious, sedated)

k) Reduction of the probability and magnitude of accidental and unintended exposures

Need to include a list of local measures that are taken to reduce the probability and magnitude of accidental or unintended exposures, which may include the following examples:

- Adherence to individual/patient identification process
- Establishment and use of DoRLs for CT planning exposures and CBCT verification imaging where appropriate
- Adoption of national IGRT protocols[126]
- Adoption of national treatment prescriptions where appropriate[56]
- Delivery of therapeutic exposures appropriately verified
- MPE involvement
- Effective communication with the patient to improve co-operation during exposures
- Culture of MDT working
- Communication with all duty holders to share learning themes and promote compliance with the employer's procedures
- Participation in IPEM regional dosimetry audits and surveys[127]
- Audit of all parts of the clinical pathway
- Monitoring compliance with employer's procedures
- Robust QA programme for documentation and equipment
- Internal and external audit
- Training and competence assessments, including when new equipment and procedures are introduced
- Analysis of trends to identify need for change in practice or procedure or need for further training

l) Informing the referrer, practitioner and patient of CSAUE

- How do duty holders identify and report radiation incidents including near misses?
- What information is required?
- How and where is this information recorded?
- Who investigates?
- Who will inform the referrer, practitioner and individual?
- How will the information be communicated (verbal, written) and where is this communication recorded?
- How and where is the decision recorded when the individual is not informed?
- How are CSAUE/SAUE notified to the relevant enforcing authority?
- How will the outcome of the investigation be shared?
- How is feedback and learning delivered to staff?

m) Non-medical exposures

- Not applicable for radiotherapy or MRT, but a statement to this effect is required

n) Carers and comforters

- Process for designating individuals as carers and comforters
- Documentation/records
- Involvement of the MPE

o) Clinical audit

- Planned annual clinical audit programme
- What is the frequency of clinical audits?
- Priorities and coverage of practice
- Interrelation of clinical audit with other quality and regulatory activities
- Is there MDT involvement?
- How is learning evidenced? How is learning disseminated?
- Outcome of clinical audits

p) Amending and cancelling referrals

- Training for referrers, if appropriate
- Description of the referral process
- Communication requirements
- Where to access the referral guidelines

Appendix 4. Criteria for clinical protocols

Fields to consider when establishing protocol templates

Field	Areas to consider and examples
Indications	• Diagnosis • Treatment intent
Essential investigations / referral guidelines	• A minimum of two of diagnostic imaging, histology or clinical examination required as baseline referral criteria from a site-specific list of appropriate investigations
Information for patients	• Benefits and risks • Expected site-specific side-effects • Site-specific written information given to patient
Consent	• Required for all patients • Consent form completed prior to localisation
Clinical trials	• Include list of appropriate trials for consideration for this disease that the provider participates in
Chemotherapy / hormone / immunotherapy	• Include regimes for this disease if appropriate
Position / immobilisation / patient preparation	• For example, supine, thermoplastic, spine straight or deep inspiration breath hold (DIBH) or patient preparation
Planning technique	• For example, planning using CT data to include slice thickness
Imaging required for GTV definition	• CT / use of contrast / MRI / CT fusion PET-CT
Dose / time / fractionation/ category (for unscheduled gaps) / number of phases	• For example, 66 Gy in 33 fractions over 6.5 weeks • For example, uninvolved nodal volumes to receive 50 Gy (CTV5000) • For example, primary and involved nodes to receive 66 Gy (CTV6600)
CTV	• For example, CTV6600 = primary tumour and involved or high-risk nodes with at least a 10 mm margin
PTV	• For example, PTV = CTV + 3 mm
Peer review of volumes	• For example, prospective peer review or retrospective quality assurance/audit[12]
Field arrangement	• For example, VMAT – 2 arcs
Use of MLC	• As required to spare normal tissue

Critical organs and tolerance doses	• Tolerance tables / DVHs
IGRT	• For example, CBCT first three fractions and weekly thereafter
IVDs	• For example, transit dosimetry day 1 and following plan changes
On-treatment review clinics	• Weekly review • To be reviewed earlier if unexpected side-effects emerge
Letter	• To be dictated at completion review by consultant
Follow-up after radiotherapy	• For example, 2 weeks at the joint oncology clinic
Arrangements for treatment summary	• Treatment summary to be entered into the OMS by treatment radiographer
Evidence base for approach	• List of references

Appendix 5. Example of a clinical oncologist training record

Please note this is an example of how a training record could be presented. The detail of examples given is not intended for direct adoption in the clinical environment. Employers should consider how the example template could be adapted to their local practice.

Sample clinical oncologist IR(ME)R training record

Document reference	**XXX V0.1**		
Policy name	Clinical oncologist training record		
Author (name and job title)	xxxxxxxxxxx		
Reviewer: (name and job title)	xxxxxxxxxxx		
Date of issue	xx/ xx / xxxx	**Review date**	xx/ xx / xxxx

Contents

1. Scope and responsibility 000
2. Aim 000
3. IR(ME)R general and annual review 000
4. IR(ME)R referral awareness training record 000
5. IR(ME)R practitioner training record 000
6. IR(ME)R operator training record 000
7. Peer review records 000

1. Scope and responsibility

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) require the employer to keep up-to-date training records for all practitioners and operators and make these available for review.

Clinical oncologists may be entitled to act in one or more of the duty holder roles as referrers, practitioners and operators.

Clinical oncologists must have a clearly defined scope of practice, and training and competency records to support their roles as operators and practitioners. While not explicitly required under IR(ME)R, it is considered best practice that referrers complete local referral awareness training prior to being entitled – that is, making, amending and cancelling referrals.

Training records should be available to support competency sign-off and link to the individual's scope of practice for which they are entitled to act.

Staff must read and understand reference documents such as employer's procedures, local departmental procedures and protocols specific to the work undertaken.

It is the responsibility of each individual to recognise and work within the limitations of their own scope of practice.

Locally entitled IR(ME)R operators, practitioners and referrers should be listed, with their scope of practice, within the quality management system *(reference specific document here)*.

2. Aim

The aim of this document is to evidence training, competency and continuing professional development for individuals to be entitled as IR(ME)R duty holders.

3. IR(ME)R general and annual review

Name:	Job title:
Registration body and number:	Checked by and date:
For brachytherapy practice confirm:	
Practitioner licence reviewed:	Checked by and date:

Nature of training	Oncologist signature / date	Trainee signature / date
Radiation protection e-learning training (ESR) – annually		
Review IR(ME)R employer's procedures – annually *(reference local procedures)*		
Review ionising radiation policy – annually *(reference local procedure)*		
Referrer scope of practice and entitlement record reviewed *(reference specific document here)*		
Operator scope of practice and entitlement record reviewed *(reference specific document here)*		
Practitioner scope of practice and entitlement record reviewed *(reference specific document here)*		
Brachytherapy – HDR local emergency training update		
Additional training needs identified		

In signing this record the individual named above confirms they have received and understood the training provided, and read and understood the reference documents.

Signature of individual / date: .....

Signature of assessor / date: .....

Completed copies of this document should be kept in the employee personnel file.
This document should be submitted as part of annual appraisal.

4. IR(ME)R referral awareness training record

Name: ..... Job title: .....

Confirmation individual is a registered healthcare professional *(eg GMC number)*: .....

Nature of training	Oncologist signature / date	Trainee signature / date
Induction only		
Access to local referral guidelines *(reference local procedure in quality management system and consider on-site and off-site access as required)*		
Access and overview to local referral system *(consider access on-site and from off-site clinics)*		
How to submit a referral *(reference local work instruction)*		
How to cancel a referral *(reference local work instruction)*		
Awareness and access to view individual scope of practice for entitlement *(reference local procedure)*		
CPD / update / refresher training		
Example: Return to practice refresher		
Example: Software update training		
Example: Significant changes to local practice		

In signing this record the individual named above confirms they have received and understood the training provided, and read and understood the reference documents.

On completion of training the named individual will be deemed competent to be entitled as an IR(ME)R referrer in the *(local radiotherapy department)* for the tasks listed above for the practices listed in their scope of practice.

Signature of individual / date: .....

Signature of assessor / date: .....

Completed copies of this document should be kept in the employee personnel file.
This document should be submitted as part of annual appraisal.

5.IR(ME)R practitioner training record

Name: ..... Job title: .....

Confirmation individual is a registered healthcare professional *(eg GMC number)*: .....

Confirmation of attainment of FRCR Part 1 date: .....

Confirmation of attainment of FRCR Part 2 date: .....

Other relevant qualification/ name and date: .....

For brachytherapy practice confirm:
Practitioner licence number
Expiry date
Procedure codes from the licence

Nature of training	Oncologist signature / date	Trainee signature / date
Induction only		
Understand local site-specific planning guidance *(reference local procedure)*		
Access agreed dose/fractionation regimes *(reference local procedure)*		
Use of local e-prescribing system *(reference local procedure)*		
Prescription approval *(reference local procedure)*		
How to amend a prescription *(reference local procedure)*		
How to stop a treatment *(reference local procedure)*		
Introduction to authorisation of a deviation from protocol *(reference local procedure)*		
Participation in peer review meetings *(reference local procedure)*		
Brachytherapy – practitioner licence management process *(reference local procedure)*		
Brachytherapy – employer licence awareness *(reference local procedure)*		
Awareness and access to view individual scope of practice for entitlement *(reference local procedure)*		
CPD / update / refresher training		
Example: Successful completion of ESTRO – Falcon Online Course – Breast Cancer *(certificate of attendance available)*		

Example: Attendance at ESTRO Multidisciplinary Management of Breast Cancer *(certificate of attendance available)*		
Example: Invited speaker at RCR study day on radiotherapy in breast cancer		
Example: Contributed to RCR consensus guidance on breast radiotherapy		
Example: Led local review of breast clinical protocol		
Example: Completed literature review as evidence basis for local breast protocol		
Example: Participation in peer review		
Example: Appointed local lead breast consultant clinical oncologist		

In signing this record the individual named above confirms they have received and understood the training provided, and read and understood the reference documents.

On completion of training the named individual will be deemed competent to be entitled as an IR(ME)R practitioner in the *(local radiotherapy department)* for the tasks listed above for the practices listed in their scope of practice.

Signature of individual / date: .....

Signature of assessor / date: .....

Completed copies of this document should be kept in the employee personnel file.
This document should be submitted as part of annual appraisal.

6. IR(ME)R operator training record

Name: ..... Job title: .....

Nature of training	Oncologist signature / date	Trainee signature / date
Induction only		
Access and overview of quality management system *(reference local procedure)*		
Access to and use of local incident learning system *(reference local procedure)*		
Access and use of local oncology management system *(reference local procedure)*		
Access and overview of treatment planning system (TPS) *(reference local procedure)*		
Overview of image fusion tools *(reference local procedure)*		
Use of contouring tools in TPS *(reference local procedure)*		
Use of expansion tools in TPS *(reference local procedure)*		
Approval processes in TPS *(reference local procedure)*		
Plan review in TPS *(reference local procedure)*		
Awareness of local image-guided radiotherapy (IGRT) protocols *(reference local procedure)*		
2D IGRT image-matching tools for entitlement *(reference local procedure)*		
3D IGRT image-matching tools *(reference local procedure)*		
4D IGRT image-matching tools *(reference local procedure)*		
IGRT image-approval tools and processes *(reference local procedure)*		
Awareness of local patient review protocols *(reference local procedure)*		
Use of patient review recording systems *(reference local procedure)*		
Brachytherapy – prostate seed insertion *(reference local procedure)*		
Brachytherapy – gynaecological applicator insertion *(reference local procedure)*		
Brachytherapy – use of ultrasound for verification *(reference local procedure)*		

Brachytherapy – access and use of TPS *(reference local procedure)*		
Brachytherapy – use of contouring tools *(reference local procedure)*		
Brachytherapy – approval processes *(reference local procedure)*		
Brachytherapy – HDR local emergency training *(reference local procedure)*		
(Include other specialist equipment such as MR linac, superficial as appropriate)		
Awareness and access to view individual scope of practice for entitlement *(reference local procedure)*		
CPD / update / refresher training		
Example: *Return to practice refresher*		
Example: *Software update training*		
Example: *Significant changes to local practice*		

In signing this record the individual named above confirms they have received and understood the training provided, and read and understood the reference documents.

On completion of training the named individual will be deemed competent to be entitled as an IR(ME)R practitioner in the *(local radiotherapy department)* for the tasks listed above for the practices listed in their scope of practice.

Signature of individual / date: .....

Signature of assessor / date: .....

Completed copies of this document should be kept in the employee personnel file.
This document should be submitted as part of annual appraisal.

7. Peer review records

Name: ..... **Job title:** .....

In addition to the training records outlined previously in this document, staff should complete a minimum of ten clinical cases for peer review as part of induction and then annually thereafter. This document is for keeping a record of completed cases and should be submitted at
annual appraisal.

Clinical competencies: Target outlining record, body site specific – minimum of 10 cases per anatomical site over a 12-month period (an exception may be made for rare and less common tumours)					**Oncologist signature / date**	**Peer reviewer signature / date**
Number	Date	Body site	Pt. no.	Peer review / volume		

In signing this record the individual named above confirms they have received and understood the training provided, and read and understood the reference documents.

On completion of training the named individual will be deemed competent to be entitled as an IR(ME)R practitioner in the *(local radiotherapy department)* for the tasks listed above for the practices listed in their scope of practice.

Signature of individual / date: .....

Signature of assessor / date: .....

Completed copies of this document should be kept in the employee personnel file.
This document should be submitted as part of annual appraisal.

Appendix 6a. Example of an entitlement matrix

Please note this is an example of how an entitlement matrix could be presented. The detail of examples given is not intended for direct adoption in the clinical environment. Employers should consider how the example template could be adapted to their local practice.

Entitled practitioner staff list – external beam radiotherapy – planning, verification and treatment exposure

Name	Adrenal	Breast	CNS	GI lower	GI upper	Genito-urinary	Gynaecology	Head and neck	Lung	Haem oncology	Paediatrics	Skin	Sarcoma	Stereotactic	Palliative whole brain	Palliative chest	Palliative bone 1st treatment	Palliative nodes	Palliative bone retreatment	Emergencies
	Consultant clinical oncologists																			
	0	3	0	1	2	0	2	1	0	0	0	3	0	0	3	3	3	3	3	3
	0	3	1	1	1	1	1	0	0	0	0	2	0	1	3	3	2	3	2	3
	0	2	3	1	1	1	3	3	1	0	0	3	0	3	3	2	3	3	3	3
	2	0	2	2	2	2	3	2	2	0	0	1	0	2	3	3	2	3	2	3
	3	1	0	1	1	3	1	0	2	0	0	0	0	0	3	2	3	3	3	3
	0	1	0	3	3	1	1	1	3	0	0	2	0	3	3	3	3	3	3	3
	Specialist registrar clinical oncologists																			
	1	2	0	0	0	2	1	0	1	0	0	1	0	0	2	2	2	2	2	2
	1	2	0	1	1	2	0	0	0	0	0	2	0	0	2	2	2	2	2	2
	1	2	0	1	1	2	0	0	0	0	0	1	0	0	2	2	2	2	2	2
	Consultant radiographers																			
	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0

Level 3	Entitled to justify (prescribe) and authorise plan for these malignancies. Under appropriate and clearly documented circumstances, can deviate from the site protocol under concession (consultant only).
Level 2	Entitled to justify (prescribe) and authorise plan if plan meets departmental constraints according to the appropriate site protocol for these malignancies. FRCR part 2 essential requirement for radical cases and FRCR part 1 essential requirement for palliative cases.
Level 1	Entitled to authorise plan if it meets departmental constraints, but not justify (prescribe) according to the appropriate site protocol for these malignancies.
Level 0	No entitlement.

- Emergencies applies to patients treated outside normal departmental hours.
- For specialist registrars: on return from periods of leave of more than six months, consultant should reassess a number of cases to ensure no additional training is required.

Author: Anne Smith	Page no: 1 of 1	Implementation date: 10/09/2025
Authorised by: medical director	Version no: 1	Next review due: 08/08/2027

Appendix 6b. Example of an entitlement matrix

Please note this is an example of how an entitlement matrix could be presented. The detail of examples given is not intended for direct adoption in the clinical environment. Employers should consider how the example template could be adapted to their local practice. .

Entitled operator staff list – treatment planning

Name	Basic use of TPS	Import of planning CT scans	Import of reference images and image fusion	OAR contouring	PTV preparation	3D plan preparation	IMRT plan preparation	VMAT plan preparation	SRT plan preparation	3D plan check	IMRT/VMAT plan check	SRT plan check	Plan evaluation	TPS QA
	Medical physics staff – operators													
	3	3	2	1	0	2	2	2	3	2	3	3	3	3
	3	3	3	2	1	2	1	1	2	2	3	3	3	3
	2	2	2	0	0	2	1	1	1	3	1	0	2	1
	2	2	2	1	0	2	2	2	0	0	0	0	2	0
	Medical physics – MPEs													
	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	1	3	3	3	3	3	3	3	3	3	3	3	3	2
	Clinical oncologists – operators													
	1	0	0	1	1	0	0	0	0	0	0	0	1	0
	1	0	0	2	2	0	0	0	0	0	0	0	1	0
	1	0	0	2	2	0	0	0	0	0	0	0	1	0
	Radiographers – operators													
	2	2	1	1	1	1	1	0	0	0	0	0	1	0
	2	2	1	1	0	1	0	0	0	0	0	0	0	0

Site-specific entitlement is listed on individual scope of practice.
Level 0: Not entitled
Level 1: Entitled to undertake this task
Level 2: Entitled to complete independent check of someone who completed this task
Level 3: Entitled to train and deem others competent in this task

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Authorised by: medical director	Version no: 1	Next review due: 08/08/2027

Appendix 7. Criteria for end-of-treatment letter

Fields to be considered for inclusion in end-of-treatment letter:

Field	Areas to consider / examples
Indications	• Diagnosis • Treatment intent
Radiotherapy dates	• Start date and end date • Any gaps/interruptions • Multiple phases
Location of radiotherapy	• Tumour site • Laterality
Radiotherapy dose schedule	• Total dose • Dose per fraction • Machine energy (eg photons, electrons) • Overall treatment time
Concomitant therapy	• Include any additional therapy appropriate for the disease site
Toxicities	• Actual acute toxicities experienced during treatment attendance • Grade of toxicity and treatment given
Expected toxicities	• Examples of acute and late toxicities • Suggestions of treatment
Performance status	• Indicates patient fitness and vulnerability
Social history	• Social support on discharge
Contact information	• Specific clinical team contact information • Departmental contact information • Out-of-hours contact information
Follow-up after radiotherapy	• For example, two weeks at the joint oncology clinic

Appendix 8a. Radiotherapy example of local risk assessment directed at accidental and unintended exposures

Please note this is an example of how a risk assessment directed at AUE could be presented. The detail of examples given is not intended for direct adoption in the clinical environment. Employers should consider how the example template could be adapted to their local practice.

Risk assessment matrix

Incident analysis from the most frequently locally reported external beam events would suggest that the main areas of local risk of unintended or accidental exposure are:

a. Positional/geographical events

b. Target volume events (ie incorrectly marking target volumes)

c. Imaging-related events (eg incorrect decision following imaging, wrong imaging factors)

d. Equipment-related events (especially XVI)

e. Incorrect referral (eg wrong patient).

Each of these categories will be risk scored using the matrix below, then risk scored again once mitigation factors are applied.

Severity

Risk rating score	Severity description	Impact on staff	Impact on organisation	Patient impact
1	No harm	• Near miss • No injury • Harm prevented	• No risk to organisation • £0–£50K loss	• No issues for patients
2	Low	• Minor injury	• Minimal risk to organisation • £50k–£100k loss	• Minor injury/minor correction needed for patient's treatment
3	Moderate	• Injury causing temporary incapacity • Additional treatment needed	• Moderate risk to organisation • Potential for adverse publicity • Minor breach of patient confidentiality • £100K–£1m loss	• Injury causing temporary incapacity • Additional treatment needed • Litigation possible • Breach of legal or authoritative guidance
4	Severe	• Injury causing permanent incapacity • Injury needing major intervention or admission to ITU • SUI	• High risk to organisation • Service restriction or closure • Severe breach of patient confidentiality • Probable media interest • £1m–£5m loss	• Injury causing permanent incapacity • Injury needing major intervention or admission to ITU • SI • Litigation expected • Prosecution risk
5	Catastrophic	• Incident causing death • SUI	• Disruption to service • Extreme risk • Major breach of patient confidentiality • Significant adverse publicity • ≥£5m loss	• Incident causing death • SI • Prosecution risk

Note: SI = serious incident; SUI = serious untoward incident

Likelihood

Likelihood score	Chance	Description
1	Rare / extremely unlikely	Very good control 0.01% chance
2	Unlikely	Good control 0.1% chance 1/3 yrs
3	Likely	Limited effective control 1% chance 1/yr
4	Somewhat likely	Weak control ≥ 10% chance 1/6 months
5	Very likely	No effective control ≥ 80% chance 1 /4 weeks

Likelihood and risk evaluation

Likelihood	Consequence				
	None (1)	Low (2)	Moderate (3)	Severe (4)	Catastrophic (5)
Rare (1)	1	2	3	4	5
Unlikely (2)	2	4	6	8	10
Likely (3)	3	6	9	12	15
Somewhat likely (4)	4	8	12	16	20
Very likely (5)	5	10	15	20	25

a. Positional/geographic events

Main areas of risk are from:

- **Incorrect isocentre positions supplied by pretreatment.** This would be mitigated by linac staff cross-checking these values against source data and by imaging the patient and performing a gross error check before treatment commences.
- **Incorrect identification of isocentre by linac staff** (eg using blemish instead of tattoo, performing wrong iso shift). This would be mitigated by linac staff performing cross-checks against source data, cross-checks of the DRR against patient anatomy and by imaging the patient and performing a gross error check before treatment commenced.

Area of risk	Initial risk			Following mitigation		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Incorrect isocentre position supplied by CT/planning	3	3	9	3	1	3
Incorrect identification of isocentre	3	3	9	3	1	3

Cannot mitigate against staff not performing the correct imaging procedure, however (consequence = 3, likelihood = 1, risk score = 3)..

b. Target volume events

Main areas of risk are from:

- **Clinician incorrectly marking the correct target volume.** This is mitigated against by two subsequent planning staff checks. Could be mitigated further with peer review of target volumes.
- **Accidental incorrect voluming as a result of mouse-generated artifacts left on CT slices.** This is mitigated against by two subsequent planning staff checks. Could be mitigated further with peer review of target volumes; however, risk score remains the same.

Area of risk	Initial risk			Following mitigation		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Incorrect marking of volume	3	2	6	3	1	3
Accidental artifact on volumes	3	2	6	3	1	3

Cannot mitigate against staff not performing the correct imaging procedure, however (consequence = 3, likelihood = 1, risk score = 3)

c. Imaging related events (eg incorrect decision following imaging, wrong imaging factors)

Main areas of risk are from:

- **Wrong imaging factors used initially** (wrong XVI filter, accidental change of energy/length of imaging time). This is mitigated against by physics staff performing extra QA on linacs to ensure imaging factors are standard and by radiographers following correct imaging protocols/checking imaging filters.
- **Data prep staff not selecting the correct imaging modality or not scheduling the correct imaging procedures.** This can only be mitigated against by ensuring continuing staff training, cross-checks within data prep/at linac and adherence to imaging protocols.
- **Linac radiographers making incorrect clinical decisions following imaging**. This is mitigated further by increased training for radiographers, audit of practice to ensure clinical decision-making is good and subsequent imaging to check actions.

Area of risk	Initial risk			Following mitigation		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Wrong imaging factors	2	2	4	2	2	4
Incorrect imaging modality/scheduling	2	3	6	2	2	4
Incorrect decision-making following imaging	2	2	4	2	2	4

d. Equipment-related events

Main areas of risk are from:

- **XVI failures resulting in rescans required.** This used to be a fault occurring 30 times per month; however, this has been mitigated by collaborative work between the RTS service and Elekta and consequent improved technology.
- **Mosaiq failures causing either rescans to be required or patient set-ups to be repeated** (which may involve a rescan). Currently, these cannot be mitigated against.
- **CT-Sim failures – mainly as a result of 4DCT failure.** These currently cannot be mitigated against any further.

Area of risk	Initial risk			Following mitigation		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
XVI failure	1	5	5	1	3	3
Mosaiq failure	1	4	4	1	4	4
4DCT issues (CT-Sim failure)	1	4	4	1	4	4

e. Incorrect referral

Main areas of risk are from:

- **Clinician selects wrong patient from Mosaiq.** This had happened quite frequently (three times/month) as a result of clinicians either selecting the wrong patient when searching by name or searching correctly but using the wrong name. Mitigation for this has been a focused effort from the clinical lead to address this with clinicians and emphasise patient ID-checking process and highlighting the risk (no events occurred for over six months since). Further mitigation can be added by the checking process of the booking office and CT-Sim checks, which may also identify if the wrong patient has been referred (but not a 100% failsafe system).
- **Clinician requests incorrect treatment.** This has happened on occasions where the referrer requests the wrong fractionation or treatment technique. Mitigation for this is more difficult as there is no cross-check that the correct dose/#/technique has been requested, unless issues of dose and fractionation are addressed as part of clinician peer review or as part of a weekly 'safety huddle'. Responsibility lies solely with the referrer. However, once the practitioner prescribes the treatment, this in itself may identify patient safety events (not 100% failsafe). Failure to identify patient safety events at the prescribing point will not cause overdose (as patient will be treated to the prescription) but unless appropriate communication is in place to ensure the appointment booking is amended, there is a chance that not enough fractions will be added to the Mosaiq schedule and this increases the chance of some appointments being missed (on the few occasions this has occurred, subsequent radiographer checks have identified this and correction made).

Area of risk	Initial risk			Following mitigation		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Wrong patient selected	4	2	8	4	1	4
Wrong treatment requested	4	2	8	4	1	4

Note: Patient ID incidents are rarely (1 in 15 yrs) a source of patient safety events so not specifically risk scored. Our three-point ID procedure is adhered to extremely well (likelihood = 1, consequence 4, risk score = 4).

Appendix 8b. Nuclear medicine therapies – example of local risk assessment directed at accidental and unintended exposures

Area of risk	The hazards	Consequence x likelihood = risk score			Controls to manage the risk	New risk score C x L = RSe			Additional actions to control risk
		C	L	RS		C	L	RS	
Patient ID process (13b)	Incorrect patient treated	4	2	8	Referral guidelines in place and available to all entitled referrers on SharePoint. Active 3-point ID check carried out independently by two operators prior to administration for all patients as required by EP A. Record of ID check on PACS. Training records of entitled operators on 3-point ID check. Referral guidelines for these therapies state all patients are seen by a licensed practitioner who completes an electronic therapy referral. Referrals are only accepted from the IR(ME)R practitioner. A list of IR(ME)R practitioner licences is available in QMS system. Radioiodine schedule with details of patients to be treated updated in local booking system and available to all relevant staff. This is updated when any amendments to schedule are made.	4	1	4	Control identified Responsible person identified Date for review agreed

Appendix 9. Working party membership

Gemma Dinn
The Society and College of Radiographers

David Eaton
Institute of Physics and Engineering in Medicine

Úna Findlay (Chair)
UK Health Security Agency

Louise Fraser
UK Health Security Agency

Mark Gaze
The Royal College of Radiologists

Spencer Goodman
The Society and College of Radiographers

Hayley James
Institute of Physics and Engineering in Medicine

Cristíona Logan
UK Health Security Agency

April-Louise Smith
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