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Clinical Oncology
The Royal College of Radiologists

Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy

Guidance from the Radiotherapy Board

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Contents

Foreword 3
1. Introduction 4
2. Duty holder roles and responsibilities 7
3. Procedures, document control and audit 19
4. Training 25
5. Entitlement 31
6. Referral process 37
7. Justification and authorisation 42
8. Optimisation 50
9. Diagnostic and dose reference levels 56
10. Patient dose assessment and recording 58
11. Clinical evaluation 60
12. Identification of the individual to be exposed 63
13. Pregnancy and breastfeeding enquiries 65
14. Communicating benefits and risks and patient information 72
15. Children and young adults 76
16. Carers and comforters 79
17. Role of the medical physics expert (MPE) 84
18. Equipment and quality assurance 88
19. Accidental or unintended exposures 97
20. Nuclear medicine licensing 106
21. Research exposures 108
References 113
Appendix 1. Glossary 119
Appendix 2. Abbreviations used in this document 125
Appendix 3. Considerations for inclusion in the employer's procedures 128
Appendix 4. Criteria for clinical protocols 133
Appendix 5a. Example of a clinical protocol 135
Appendix 5b. Example of a clinical protocol 137
Appendix 6. Example of a training record 140
Appendix 7a. Example of an entitlement matrix 142
Appendix 7b. Example of an entitlement matrix 143
Appendix 8. Criteria for end-of-treatment letter 144
Appendix 9. Example of local risk assessment directed at accidental and unintended exposures 145
Appendix 10. Working party membership 151

Foreword

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 (Great Britain) and Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 are legislation intended to protect the patient from the hazards associated with medical exposures to ionising radiation.[1,2] They replace the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (in Great Britain and Northern Ireland) and the Medicines (Administration of Radioactive Substances) Regulations 1978.[3,4] The updated regulations retain the four duty holders identified in IR(ME)R 2000: the employer, referrer, practitioner and operator. The responsibilities of each duty holder are defined in the regulations. The principles of justification, optimisation and adequate training of practitioners and operators remain fundamental to the updated regulations, with some new requirements included.

The Radiotherapy Board brought together representatives from The Royal College of Radiologists (RCR), the Society and College of Radiographers (SCoR), Institute of Physics and Engineering in Medicine (IPEM), British Nuclear Medicine Society and Public Health England to form a Working Party to produce a guide to help employers and healthcare professionals understand and implement IR(ME)R as it pertains to radiotherapy in the UK.

In 2008, a joint RCR, SCoR and IPEM document was published offering guidance on IR(ME)R for the radiotherapy community, including external beam and brachytherapy treatments.[5] This was well received and became a cornerstone guidance document. Similar guidance has not been previously available for the molecular radiotherapy (MRT) community, but this current document seeks to address this omission. In parallel the diagnostic and interventional radiology guidance was updated to reflect the new regulations and to include diagnostic nuclear medicine.[6] Every effort has been made to provide a consistent approach between these two documents with shared working across the disciplines. This new Radiotherapy Board guidance has been written in support of all staff groups involved in medical exposures within the clinical setting, in both the NHS and the independent sector.

We would like to thank members of the working party for their time and expertise in developing this guidance. In addition, acknowledgement and special thanks for their contributions go to members of the Patient Safety in Radiotherapy Steering Group and Diagnostic and Interventional Radiology and Nuclear Medicine IR(ME)R Working Party. We would also like to thank the referees for their helpful comments.

Finally, we hope this document supports the radiotherapy communities, including brachytherapy and MRT, in the effective implementation of IR(ME)R in clinical practice.

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1. Introduction

This guidance document is intended to provide a practical approach to implementing the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R)[1] for all staff groups delivering a range of radiotherapy services including molecular radiotherapy (MRT). This guidance also applies to the implementation of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 and any reference to IR(ME)R can be taken to refer to these regulations also, unless specifically stated. Within the UK, responsibility for healthcare is devolved and different approaches may be taken in each of the four nations.[2]

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. A glossary of terms is included in Appendix 1. This document should be read in conjunction with IR(ME)R and other published guidance.[7]

The regulations

IR(ME)R implements the medical exposure provisions from the European Council Basic Safety Standards Directive 2013/59/Euratom (BSSD).[8] The BSSD takes into account the recommendations from the International Commission on Radiological Protection (ICRP) publication 103.[9]

IR(ME)R includes new requirements relating to the following:

- Reporting of accidental and unintended exposures, which now includes doses that are less than intended in radiotherapy (see Chapter 19)
- A study of the risk of accidental or unintended exposures (see Chapter 19)
- Introduction of a formal recognition scheme for medical physics experts (MPEs) (see Chapter 17)
- Introduction of licensing for employers and practitioners for the administration of radioactive substances to persons for diagnosis, treatment or research (see Chapter 20)
- Existing equipment requirements moved from the Ionising Radiations Regulations 1999 and new equipment requirements from BSSD added (see Chapter 18).[3]

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

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 (for example 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.[7] Examples include:

- Health assessment for employment, immigration or insurance purposes
- Radiological age assessment
- 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 policy or similar. Further guidance on exposures as part of health screening programmes is available.[6]

2. 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 professional 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).

An individual may be entitled to act as more than one duty holder, 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 signed for by the person responsible. Further detail on supervision can be found in Chapter 4.

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

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 (for example referral), but they cannot be held responsible for those tasks carried out by other duty holders (for example justification).

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.[10] 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), radiological information system and picture archiving communication system (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).[11]

Scenario 1

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

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

The employer's procedure should indicate where the responsibility lies for this specific task.

Scenario 2

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

A clearly defined written procedure setting out what constitutes a prescription, and what the practitioner signing the prescription is taking responsibility for, allows individuals who also contribute to the planning tasks to be clear about what they are responsible for and what the practitioner is responsible for. For example, one clinician performs part of the planning process (such as prescribing) and another clinician accepts the dosimetry and authorises the plan against a protocol so that the patient can proceed to treatment. In this situation, a clinical oncologist who is authorising the plan for use is acting as an operator.

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

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.

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) ▪ Have a QA programme in place for documentation (see Chapter 3) ▪ Establish written protocols for standard radiological practices ▪ Establish referral guidelines ▪ 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	Requirement	Things to consider
Regulation 7	Clinical audit	▪ Ensure the employer's procedure details how and when clinical audit is carried out and results are disseminated to employees (see Chapter 3)
Regulation 8	Accidental or unintended exposures	▪ Ensure 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 ▪ Investigate, record and report radiation incidents where an accidental or unintended exposure has occurred (see Chapter 19) ▪ Establish a study of the risk of accidental or unintended exposures
Regulation 12(9)	Clinical evaluation	▪ Ensure a clinical evaluation is recorded for every exposure except for carers and comforters (see Chapter 11)
Regulation 14(1)	Expert advice	▪ Appoint a suitable 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)

Regulation	Requirement	Things to consider
Schedule 2	Written employer's procedures	▪ A minimum requirement of 14 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 should be the chief executive unless an alternative individual has been formally designated to do so. 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.

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, 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.

Referrer

The referrer must be a registered healthcare professional as defined in IR(ME)R.[12] 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 from whom they will accept referrals 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 2.2.

Table 2.2: Requirements of the referrer

Regulation	Requirement	Things to consider
Regulation 6(2)	Written procedures are complied with by the referrer	▪ Ensure referrals comply with employer's referral guidelines ▪ Referrer awareness training (see Chapters 4 and 6) (eg, process for amending or cancelling a referral)
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(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 ▪ 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

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

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.

The possibility of alternative modalities that do not involve exposure to ionising radiation must be taken into account. The roles and responsibilities of the practitioner are set out in Table 2.3.

Table 2.3: Requirements of the practitioner

Regulation	Requirement	Things to consider
Regulation 10(1)	Employer's procedures	▪ Read and comply with employer's procedures
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 of the licence ▪ Ensure that it is kept up to date
Regulations 10(2), 11(2), 11(3) and 11(4)	Justification of the exposure	▪ Weigh up benefit and risk ▪ 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 referrals that are justified ▪ Consider justification of exposures to carers and comforters (see Chapter 7) ▪ Consider the urgency of the exposure ▪ Document relevant information

Regulation	Requirement	Things to consider
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 (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
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 specific procedures.

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 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 radiopharmaceuticals
- Image manipulation and archive
- QA of radiation equipment
- Clinical evaluation
- Clinical patient review.

Operator functions may be carried out by clinicians, radiographers, the MPE 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)].

Third-party service engineers would not normally be entitled as operators. In most circumstances, third-party engineers, whether providing initial installation or servicing, 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. The roles and responsibilities of the operator are set out in Table 2.4.

Table 2.4: 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 provided 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

Regulation	Requirement	Things to consider
Schedule 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.

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 (for example clinical technologists) through accreditation by the Academy for Healthcare Science (AHCS) or 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]

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.

3. 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 and Appendix 5 includes examples of clinical protocols.

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 error and to increase the probability that any errors 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]

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 QMS, which might be defined as a formalised system that documents processes, procedures and responsibilities for achieving objectives. External review and accreditation schemes for QMS are available (for example International Standard ISO 9001:2015)[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.

Table 3.1: Considerations when establishing a QA programme

QA programme	Things to consider
How are 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 source documents 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 ▪ Regular feedback to governance teams

QA programme	Things to consider
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, signature, date of approval and next review date
How frequently should reviews occur?	▪ Every two years or following change in technique/ 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 accidental or unintended exposures in radiotherapy [Regulation 8(2)]. This is discussed further in Chapter 19.

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. IR(ME)R audit might be included as part of the clinical audit programme as required under Regulation 7. Some examples of audits are included in Table 3.2 below, but this list is not exhaustive.

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

Audit	Things to consider
Appropriateness of referrals	▪ 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? ▪ Appropriate feedback should be provided to referrers, and corrective actions should be taken where nonconformance reoccurs.
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?
IR(ME)R operator/ practitioner/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/ 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/authorising operator? ▪ Is the operator authorising appropriately and within the authorisation procedure?
Clinical evaluation	▪ Is there evidence of a written clinical evaluation in a sample of patient records for the treatment and concomitant exposures?

Clinical audit

Regulation 7 requires the employer to have in place a programme for clinical audit. 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, re-audited to ensure the corrective action has had the desired positive effect.

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.

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.[28] 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 continuous 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.

Scenario 3

A department develops a volumetric modulated arc therapy (VMAT) technique for planning radical radiotherapy. This new technique is used to treat patients with rectal cancer. The change of technique could reduce radiation dose to OAR and reduce toxicity. A clinical audit is designed by the multiprofessional team involved in the treatments. The audit is supported and approved by the employer and implemented prospectively. The data collected is analysed and compared with the previous radiotherapy technique to justify a change in practice. It is subsequently shared with the wider radiotherapy community. The audit is presented at national multiprofessional meetings to add to the available body of evidence.

4. 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 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)]. This includes undertaking continuous education and training after qualification and 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 continuous development 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. An example of a training record is included in Appendix 6.

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 (for example a linear accelerator or TPS), there may be differences in the way it has been commissioned that affect its use.

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.

Regulation 17(5) requires employers to co-operate with regard to the training records for locum and agency staff. 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 equally to locum and agency staff as to permanent employees.

Scenario 4

A radiotherapy department utilises agency therapeutic radiographers. The agency employing the individuals is responsible for keeping and maintaining up-to-date records of all previous and ongoing education and training. The employer entitling the individual to act as a practitioner or operator requests these records and they are made available. The department employing the individual reviews the training records as a matter of good practice, including those held by the agency. Such staff also receive adequate training within the local department.

Adequate training

Schedule 3 of IR(ME)R outlines the areas of theory and practice necessary for the training of practitioners and operators that would be considered adequate. It also 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.

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, selective internal radiotherapy (SIRT) or use of 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.[29–32]

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.

Continuing education and training

Regulation 6(3)(b) requires the employer to ensure that all entitled practitioners and operators undertake continuing education and training. Such training should be relevant to an individual's role and function and related to any service or role development. In particular,

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 continuous – the introduction of new equipment, new software or the upgrade of existing software and systems has associated training requirements. In order to maintain their professional registration,[33,34] 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.

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. 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)].[35,36] The practitioner licence is issued on the basis of specialist training and experience.[35] 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.

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, for example staff and 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.[37] 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.

Scenario 5

A specialist registrar with FRCR Part 1 has local training and, following successful completion of local assessment, is entitled for the justification of radical and palliative CT planning exposures for all treatment sites at Hospital A. They are also trained and entitled for the justification of palliative treatments for spinal cord compressions and the associated on-treatment imaging as defined in the local clinical protocol.

The same individual also works at Hospital B, where they have a more limited scope of practice and are trained and entitled for the justification of palliative CT planning exposures only.

Operator training records

Training records for operators should be detailed and up to date, reflecting training and competency achieved as they learn different skills. 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.

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 GB, or the Department of Health in NI. The Department of Health and Social Care has established a UK-wide MPE recognition scheme and appointed RPA2000 as the assessing body.[38,39] The employer must appoint suitable MPEs and ensure they are involved to the extent required by Regulation 14(2).

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.

Scenario 6

A clinical oncologist is trained and entitled as a practitioner for the radical and palliative prostate external beam radiotherapy pathway. This allows them to justify the treatment and concomitant exposures associated with the delivery of external beam radiotherapy for this disease as defined in the local clinical protocol. Any deviation from the protocol should be justified and documented as per employer's procedures.

So that the same individual can undertake the outlining of the planning target volume (PTV) and associated OAR as defined in the local protocol, they are trained and entitled as an operator for these specific functions. In addition, they are trained and entitled as an operator for other functions such as patient identification, use of the TPS for plan review and sign-off, review of concomitant imaging exposures and patient clinical review.

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

Scenario 7

Treatment planning can only be carried out by an adequately trained, entitled operator. A trainee can undertake treatment planning under direct supervision of a trained and entitled operator who is responsible for the task being completed correctly. This equally applies to operators who are being trained in an additional task or competency. The nature of training will depend on the previous experience of the trainee, and may begin by preparing some plans together, followed by the trainee preparing further plan(s) themselves before the trainer reviews them, provides feedback for modification as needed, and when acceptable uses their electronic approval to indicate they are taking responsibility for the final plan.

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 to carry out an exposure. 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 (for example a student radiographer or trainee APs) 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.

There is guidance available from the professional bodies on what constitutes adequate supervision of trainees.[13,40,41] Inappropriate supervision arrangements may put the patient/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 not necessarily trained in radiation protection, the scope of their entitlement, as both practitioner and operator, should be commensurate with their training, knowledge and experience. 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.[42,43]

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.

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:

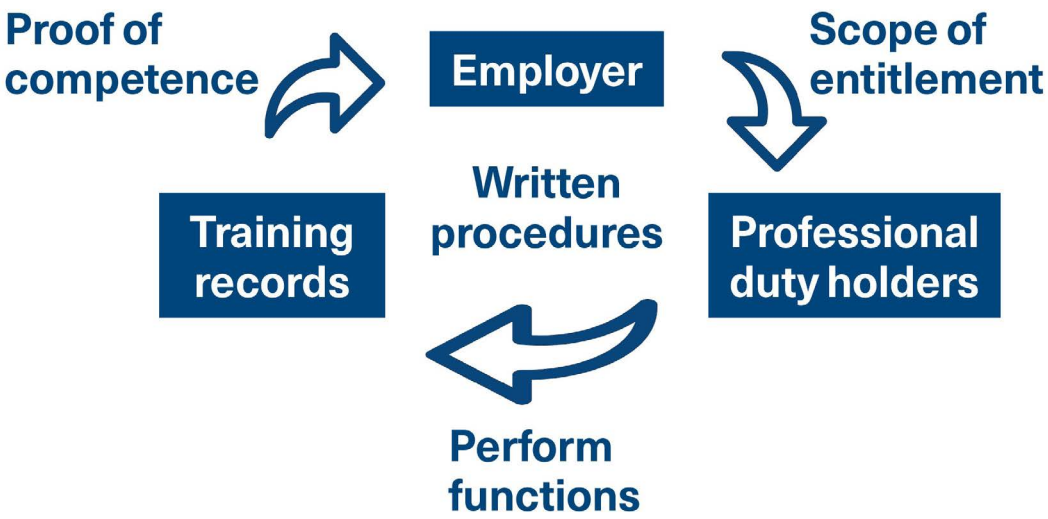
- Alert the referrer when additional information is required
- Alert the referrer that an exposure has not been justified
- Alert the referrer that a patient is not contactable
- Ensure referrals are appropriately prioritised and expedited as required
- Manage future appointments at specific time intervals, 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.

5. 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 continuous professional development.

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 7. Table 5.1 includes matters to consider for inclusion within the employer's procedure required under Schedule 2(b).

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 responsibility
Lines of IR(ME)R accountability and delegation of tasks throughout the organisation	▪ Clear governance structure ▪ Others outside the local radiotherapy or nuclear medicine department
Responsibilities of IR(ME)R duty holders	▪ 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	▪ State relevant qualification (eg, FRCR Part 1 for clinical oncologists, BSc(Hons) or equivalent for radiographers, MSc for clinical scientists) (see Chapter 4)
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[12]
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
How entitlement/scope of practice is updated and reviewed	▪ Process for reviewing and updating entitlement/scope of practice ▪ Specified timeframe (eg, at appraisal or when scope of practice changes) ▪ Who is responsible for auditing and reviewing entitlement/scope of practice

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 from 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 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 PTVs and OARs for specified groups of patients in the TPS.

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, clinical technologist and in-house engineer 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[44,45] ▪ 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 17)
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
Group entitlement For example, radiographers who clinically evaluate verification images **Entitle as operators**	▪ 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

Professional roles and duty holders	Things to consider
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 responsibilities are clearly defined for each aspect of the care pathway
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 ▪ Induction programme should include training records for locally delivered training ▪ Agency should be able to provide training records on request ▪ Audit of practice

Third-party providers

The employer's procedure should consider the entitlement and scope of practice of IR(ME)R duty holders from a third-party provider.

Staff employed by third-party providers need to be entitled as:

- Referrers, if they are referring patients on to the radiotherapy pathway
- Practitioners, if they are carrying out the justification process
- Operators, if they are performing other practical aspects such as treatment planning or delivery.

Entitlement can either be on an individually named basis or as a group entitlement. For group entitlement, the employer must be able to identify each individual in the group and be assured that they are registered, trained and competent to perform the tasks.

Operators carrying out exposures need to be aware who the practitioner is for each exposure before it is performed.

For situations where there is more than one employer involved in a care pathway, it is important from a governance perspective that each employer understands and identifies who has IR(ME)R responsibility at each point in the pathway. This detail could be included in the employer's procedures or in the contract between the two employers. However, it should be clear for all individuals involved.

When individuals work across multiple sites with multiple employers, they are required to be appropriately entitled at each site by each employer.

The process of entitlement involves:

- 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 holders performing their functions and undertaking continuous professional development.

Scenario 8

A consultant clinical oncologist is entitled as a referrer and practitioner for radical and palliative external beam treatment of gynaecological cancers at Provider A. The consultant is also entitled by Provider A as an operator for practical aspects of the treatment planning and delivery for gynaecological cancers outlined within a specific scope of practice. These practical aspects include the use of the TPS for the purposes of outlining PTV OARs, evaluation of dose distributions and review of verification imaging.

Provider A does not have a brachytherapy service; instead it has a service level agreement with Provider B for the provision of brachytherapy services that details responsibilities under IR(ME)R for each part of the care pathway.

The same consultant clinical oncologist is entitled as a referrer and practitioner for radical and palliative brachytherapy treatment of gynaecological cancers at Provider B. This extends to entitlement as an operator for the associated practical aspects of gynaecology brachytherapy planning and delivery.

This results in the individual working to two separate employer's procedures and two separate sets of records of entitlement and local training.

Scenario 9

Providers A and B both provide radiotherapy services for patients with gynaecological disease. Provider A has an external beam service but no brachytherapy service. Therefore, patients from Provider A requiring brachytherapy are referred to Provider B for this aspect of their radiotherapy. The providers have a service level agreement in place that includes a service specification and details responsibilities under IR(ME)R for each part of the care pathway. A consultant clinical oncologist is entitled as a referrer, practitioner and operator for radical and palliative external beam treatment of gynaecological cancers at Provider A within a specific scope of practice. The same consultant from Provider A is entitled as a referrer for radical and palliative brachytherapy treatment of gynaecological cancers at Provider B. Appropriately entitled practitioners and operators at Provider B undertake the planning and treatment delivery of referred patients.

6. 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.

IR(ME)R places a number of requirements on individual duty holders involved in the management of referrals to a patient pathway and these are included in Table 6.1.

Table 6.1: Considerations for the requirements of the employer and duty holders

Regulation	Things to consider
Employer 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 working in areas outside the main department) ▪ Process to ensure referrers understand their scope of practice and responsibilities under IR(ME)R ▪ Audit quality of referrals (including shared learning)
Referrer must supply sufficient medical data for practitioner to enable justification **Regulation 10(5)**	Essential information to be included on referral: ▪ Accurate, current patient demographics ▪ Confirmed clinical diagnosis (eg, confirmed histology and imaging report) ▪ Relevant clinical history ▪ 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 ▪ Timing of treatment

Regulation	Things to consider

Regulation 10(5) (contd)	▪ MRT
	  ▪ 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
	▪ Information related to research trial (where relevant)
	▪ Information related to pregnancy and breastfeeding (where relevant)
	▪ Signature of referrer

Practitioner must consider any relevant medical information supplied by the referrer in order to justify each individual exposure and to avoid any unnecessary exposures **Regulation 11(4)**	▪ Process for contacting referrer ▪ Documentation of discussions with referrer ▪ Process for returning incomplete referrals ▪ Signature of practitioner

Referrals come via a number of routes including the MDT, follow-ups in clinic and ward rounds. Confusion has arisen in the past because the term 'referral' is well understood in the context of one healthcare professional requesting that a colleague takes forward the management of a patient based on either a confirmed or suspected diagnosis.

In practice, an appointment is made for a patient to see a clinical oncologist or a member of an MDT for an opinion on the management of the patient. If, as the result of such an appointment, the patient requires radiotherapy treatment, a radiotherapy request or booking form will be completed or this information will be entered into the patient's notes. This request for a patient to be exposed to ionising radiation constitutes a referral in the context of IR(ME)R. This is particularly pertinent when patients are referred between radiotherapy centres within regions or across borders for specialist radiotherapy services.

Referral guidelines

The employer must establish referral guidelines [Regulation 6(5)(a)] and entitle individuals to act as referrers for radiotherapy for a defined scope of practice. Good practice ensures that the clinical oncologist is involved in the MDT. Where treatment referrals do not come directly from clinical oncologists, the employer's procedures should state that referral can only be justified by a clinical oncologist (or an appropriate practitioner licence holder) as practitioner. MDT referrals should include the name of the individual making the referral.

The employer must ensure referral guidelines are available to referrers. 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 of the dose associated with the exposure.

In radiotherapy, these guidelines are commonly developed as clinical protocols and MDT patient pathways, supplemented by local departmental protocols (see Appendices 3 and 4) for urgent and palliative treatments. Consideration needs to be given to ensuring these are available remotely, for example at outlying clinics run away from the local clinical service.

In establishing the referral guidelines, it is recommended to consult and agree these with professionals involved in medical exposures. 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.

Referral guidelines are required for concomitant exposures where these are not included within the radiotherapy protocol or where separate justification is required. The common approaches in use throughout the UK to refer a patient for concomitant exposures are:

- Referral for planning, treatment and verification exposures is carried out by a clinical oncologist, who usually also acts as the practitioner, or other entitled registered healthcare professional
- Exposures are defined in a verification imaging protocol, which may include both standard frequencies (for example 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 deliver additional verification or replanning exposures, up to a maximum number, if there are patient set-up or technical problems
- Registered healthcare professionals are entitled by the employer to refer patients for a defined scope of concomitant exposures. 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.

Referral guidelines must also include the expected radiation dose associated with the exposure being requested. This requirement extends to the range of exposures conducted in radiotherapy.

Information required for a referral

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 finding and staging examinations will be made available
- Laterality.

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 within clinical protocols specified by anatomical site. It is not safe to rely on sources of information other than the above. The primary source documents or copies should be available throughout the radiotherapy process, particularly at critical points such as planning and prescription. Appendices 3 and 4 demonstrate how referral guidelines for treatment exposures might be included in a site-specific protocol.

Scenario 10

The clinical oncologist (operator and practitioner) is called to the planning room to outline a left tonsil CTV and to complete the prescription for treatment. The histopathology report and MRI scans are not available in the planning room as required by the local referral criteria. The PACS and Healthcare Improvement Scotland (HIS) systems 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 is available.

Patient referrals for additional planning or verification images outside those included within the clinical protocol should include relevant clinical information to allow the practitioner to justify the exposure. The written procedures should describe how this is carried out and documented.

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. Discretion about when an operator should then ask this question of patients could be defined in a protocol.

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.

SCoR has developed a *Pause and check* poster specifically for radiotherapy referrals.[46] This highlights some key checks that should be undertaken as part of the referral process.

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

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. Some of the initial receipt and processing of referrals may also fall to non-IR(ME)R duty holders such as administrative staff. Consideration should be given to the training of administrative staff involved in the processing of referrals to ensure these are completed in a timely and consistent manner. This is discussed further in Chapter 4.

Referral systems

The use of electronic referral systems is widespread and increasing, though some employers still accept handwritten referrals from a number of specified sources and therefore run a dual electronic and paper referral system. These different processes should be clearly described in the employer's procedures.

Electronic referral systems require the referrer to log in using a unique identifier. RCR guidance suggests that an employer's procedure should ensure it is a disciplinary offence to use someone else's log-in to initiate a referral.[47] The employer's procedure should address potential safety risks when using paper or electronic referral forms.

The increased efficiency that may be seen from using an electronic referral system must be balanced with the potential for requesting exposures for the incorrect patient. Having a process in the department's audit programme for regularly reviewing the quality and accuracy of referrals from specific sources is one method of monitoring and understanding where additional referrer education or training may be required.

Electronic referral systems and paper-based systems should be fit for purpose to ensure those tasked with the administration, justification, authorisation and practical aspects of the referral to diagnosis pathway can fulfil their responsibilities.

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.

7. Justification and authorisation

Justification

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

Justification is an intellectual activity and is the primary role of the practitioner. Justification must be completed for each individual exposure that applies under IR(ME)R. For radiotherapy these will include planning, verification, treatment and research exposures in addition to exposures to carers and comforters. Carers and comforters are considered in Chapter 16.

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 from the exposure. Where the exposure involves the administration of radioactive substances, Regulation 11(1)(a) says that this may not be carried out unless the employer and practitioner hold an appropriate licence.

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.

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?
- Will the treatment control disease or alleviate symptoms?
- Are there alternative options that do not involve ionising radiation?

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

Scenario 11

During the weekly thoracic oncology MDTM, there is a discussion around the most appropriate treatment for a patient with a lung tumour. Diagnostic imaging and histology are reviewed. Potential treatment options include surgery, radiofrequency ablation and stereotactic ablative radiotherapy (SABR). The potential benefits and risks for the individual patient are weighed up for each treatment, with consideration of their histology, stage, fitness co-morbidities, staging examinations and personal situation. It is decided the patient meets the referral guidelines and should be recommended for SABR. The clinical oncologist refers the patient for a CT planning scan and acts as practitioner for the planning exposure and subsequently for the treatment and concomitant exposures for this patient.

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.[9,48–54] 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.

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. Children and young people are more sensitive to the carcinogenic risks of radiotherapy, with children being ten times higher risk compared with older individuals. They will therefore require special consideration. This is discussed further in Chapter 15.

For radiotherapy, these issues 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.

The practise of medicine always involves assessing risk and benefit. Radiotherapy is an effective and appropriate curative or palliative anticancer treatment for many patients. There are clear benefits.

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

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 or pregnancy 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?

IR(ME)R Regulation 11(2)		Things to consider
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 timeframe?

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 would usually recommend delaying treatment 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.

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, choosing an alternative radiopharmaceutical that is not secreted in breast milk and ensuring the purity of the radiopharmaceutical. Further guidance is available in Chapter 13.

Authorisation

Authorisation is a process separate to justification and is the documentation confirming that the intellectual activity of justification has taken place. 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)]. 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.

Where it is not practical for a practitioner to review every concomitant exposure request, the regulations allow for an appropriately entitled operator to authorise an exposure following authorisation guidelines that a practitioner has written. Standard concomitant exposure should be part of the clinical protocol for each treatment site and it is useful to specify some level of additional imaging as required for optimisation by operators as described below. In practice, it is most common that the practitioner authorises a course of treatment under protocol and this includes all pretreatment imaging, treatment exposures and verification imaging.

It is recommended that the practitioner's guidelines are referred to as authorisation guidelines, rather than justification guidelines, so the purpose of the document is clear. The practitioner is responsible for the justification of any exposure that is authorised by an operator following the authorisation guidelines. The operator is responsible for authorisation and for following the authorisation guidelines accurately. Where the details within a referral fall outside the criteria listed in the authorisation guidelines, the operator cannot authorise the exposure and justification by a practitioner is always required.

Authorisation guidelines

Authorisation guidelines must be produced by a single named practitioner (often, but not always, the site- or modality-specific lead oncologist or lead licensed practitioner for MRT). The practitioner who produces the authorisation guidelines takes responsibility for justification of each individual exposure authorised by operators following these guidelines. If this person 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. The author and review/revision dates should be clearly stated. The authorisation guidelines should be evidence based, reflect the most current accepted practice and take into account local service provision. Authorisation guidelines should be clearly written using precise statements that are unambiguous in order to allow the operator to confirm whether the referral can be authorised. Authorisation guidelines must be subject to document QA as described in Chapter 3.

There may be a set of authorisation guidelines for each anatomical area or type of administration, each produced by a different practitioner. However, where they are issued, the operator following the guidelines must be clearly identified and appropriately entitled as specified in the employer's procedures. It must be possible to identify the individual practitioner for each exposure performed and who has authorised the exposure.

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 12

A patient has been referred for ^{177}Lu 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 pretreatment exposures

Documented authorisation must be provided prior to planning exposures being made. This can be achieved by having a nominated signature or electronic password on the radiotherapy referral to clearly indicate the practitioner has authorised the pretreatment exposures. Procedures should make this clear.

It must be remembered that the task carried out by the practitioner is different from that of the referrer. Although it is routine for many 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.

Local protocols may allow for repeat planning exposures in specific cases (for example inadequate bladder filling). However, it should be noted that there must be a maximum number of exposures documented in the protocol. The practitioner must be able to justify the exposures included and therefore this cannot be open-ended.

If additional pretreatment exposures are required other than those set out in the clinical protocol, a procedure must be in place specifying how and by whom justification is carried out and where it is documented.

Scenario 13

A 45-year-old patient with early stage breast cancer is referred for postoperative radiotherapy from the MDT and referral is completed by a therapeutic radiographer (appropriately entitled referrer within a clearly defined scope of practice). The pretreatment exposure is authorised by the same therapeutic radiographer (adequately trained and entitled operator within a clearly defined scope of practice). The therapeutic radiographer is authorising under guidelines approved by the lead breast radiation oncologist that outline which groups of patients proceed to radiotherapy.

Authorisation of treatment exposures

Written procedures should clearly define how authorisation of treatment exposures is completed. Most usually the electronic or manual signature included in the prescription provides the evidence of authorisation of the treatment exposures. Without this clarity, there can often be differing opinions among staff in a department about what a signature on a treatment prescription means.

Consideration needs to be given to how the anatomical treatment volume (for example left breast) included in the treatment prescription is linked to the outlined treatment volume (PTV) as part of the localisation process. Local procedures should describe who is responsible for these tasks and how these volumes are linked.

Scenario 14

In a paperless department, a head and neck cancer patient was entered onto the radiotherapy pathway. The target volumes and OAR were outlined by the clinical oncologist registrar (operator) and peer reviewed by the consultant clinical oncologist (operator). The plan including the prescription was approved electronically 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 the verification imaging defined within the head and neck imaging protocol.

Scenario 15

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 recontouring and plan reoptimisation based on this image performed by entitled operators (who might include the clinical oncologist or therapeutic radiographer). The planning objectives are clearly defined and, provided each planning objective is within specified limits compared with the original plan, the clinical oncologist (operator) can authorise the plan. If the new plan exceeds these criteria, the plan should be reviewed by the clinical oncologist (practitioner), who will authorise the replan. This process is clearly defined under local authorisation guidelines.

Authorisation of verification exposures

Exposures that will always be carried out as part of a particular treatment protocol should be taken into consideration when the treatment as a whole is justified. The verification exposures are then justified by the practitioner who prescribes the treatment as part of a defined set of verification exposures for a particular technique prior to treatment commencing. The authorisation of verification is usually included in the prescription. This allows for full consideration of dose to critical structures collocated with the planning target volume.

However, it should be noted that there must be a maximum number of exposures documented or reference made to an approved protocol of verification exposures. The practitioner must be able to justify the exposures included within the protocol and therefore this cannot be open-ended.

Any verification imaging protocol should also be approved by an entitled practitioner. It is good practice for this to be done by the lead oncologist for the particular area: these protocols should be evidence based, reflecting current practice and local equipment. However, this does not represent the justification of an individual exposure that is required by IR(ME)R.

Where the justification of verification exposures is carried out separately to the justification of the treatment exposures, the employer's procedure should specify the process to follow.

If additional verification or correction exposures are required other than those set out in the imaging protocol, a procedure must be in place specifying how and by whom justification is carried out and where it is documented.

Scenario 16

A patient has been planned for prostate radiotherapy and a prescription completed by the clinical oncologist (adequately trained and entitled practitioner, within a clearly defined scope of practice). In accordance with local protocols the prescription includes authorisation of the daily verification imaging. The verification imaging procedure for external beam prostate radiotherapy includes a daily image and one additional exposure for correction purposes if required per day. Due to a difference in bowel position and gas, the patient requires one additional exposure, which is authorised by the radiographer following the authorisation guidelines (appropriately entitled operator, within a clearly defined scope of practice). The department protocol states that any further verification imaging requires separate justification and authorisation is required from an appropriately entitled practitioner. The authorisation for the additional image is annotated in the patient electronic record by the clinical oncologist.

Communication of benefit and risk

Chapter 14 discusses requirements surrounding the communication of benefits and risks of the exposure with the individual and the role of consent. There are acute, medium-term and long-term side-effects with which staff should be fully familiar from their training. Training will also be required in the communication of these issues with individuals.

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. Further guidance is given in 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.

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 being examined**	▪ 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, however, still requires individual justification and authorisation.

8. Optimisation

Optimisation is a key principle of the radiation protection framework within IR(ME)R and is required for all medical exposures. Optimisation requires a multidisciplinary approach. Effective communication and teamwork between staff groups is 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.

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 standard operating protocols should be determined through an optimisation process, operators are still required to use their professional judgement to adjust technique and parameters according to the individual patient characteristics. 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	Things to consider
Target volumes (eg, GTV, PTV)	▪ Individually planned ▪ Delivery appropriately verified
Non-target volumes and tissues (eg, OARs)	▪ ALARP ▪ Consistent with the intended radiotherapeutic purpose

Scenario 17

A bariatric patient is being treated for palliative spine metastases, but when the verification image is taken very little contrast information can be seen. The treatment radiographers evaluate the image and decide that there is insufficient information for accurate matching. They select a higher-dose protocol and repeat the image, which then allows image matching and treatment of the correct vertebral area.

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: Considerations for optimising exposures in general

General areas of optimisation	Things to consider
Training **Regulation 17(1)**	▪ A robust training programme must be in place to ensure all practitioners and operators are competent and aware of how to use existing, new or updated equipment
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
Quality assurance (QA) **Regulations 6(5), 12(3) and 15(1)**	▪ Established QA programmes are required for both written procedures and equipment or methods (see Chapters 3 and 18 for more details)
Clinical audit **Regulation 7**	▪ Image quality, technique (eg, use of accessory equipment), protocols, doses or image analysis may be audited and practice changed based on evidence ▪ Introduction of new procedures and techniques should be audited in a timely manner to ensure optimisation is achieved
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
Clinical evaluation **Regulation 12(9)**	▪ There should be a clinical evaluation of the outcome of each exposure (see section below and Chapter 11)
MPE involvement **Regulation 14(3)(a)**	▪ MPE should be consulted on optimisation (see Chapter 17 for more details)

General areas of optimisation	Things to consider
Research programmes **Regulation 12(4)**	▪ Volunteers for research should be informed of the risks and individually planned, as with non-research exposures (see Chapter 21)
Sealed and unsealed source therapies **Regulations 12(6) and 12(7)**	▪ Capacity to consent ▪ Guidance on limiting dose to others the patient may come into contact with after leaving the department (see Chapters 14 and16)
Carers and comforters **Regulation 6(6)**	▪ Adherence to dose constraints specified in employer's procedures (see Chapter 16)

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[55] ▪ 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

Particular attention when optimising	Things to consider
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 (sealed sources) are individually planned in terms of expected radiation dose. Typically, doses are calculated using a computerised TPS based on dedicated imaging data (for example 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 (for example VMAT, 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.

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.[7] *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
- Use of standard activities where this is consistent with professional guidance.

Scenario 18

In a clinical trial, a child with metastatic neuroblastoma is to be treated with ^{177}Lu DOTATATE. A baseline ^{68}Ga PET-CT has been performed, which has shown tracer uptake (SUVmax) 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.

Concomitant exposures for 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. This includes at installation or upgrade of equipment, and at regular intervals based on dose audits. National dose reference levels are increasingly available for comparison with local DRLs to aid optimisation (for example, for planning CT exposures).[56]

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.

Scenario 19

Additional CT planning protocols are created to account for bariatric patients, using higher kV as well as higher mAs thresholds to give adequate image quality for delineation. A pathway is established to identify patients based on body mass index greater than 40, to predict in advance who will benefit and reduce the need for repeat exposures.

Clinical evaluation

All medical exposures should be evaluated in terms of their outcome, including recording of doses delivered, to ensure exposures were appropriate. Further detail is available in Chapter 11.

Scenario 20

A bariatric patient received a CT scan using the standard pelvic protocol for the localisation of a gynaecological cancer. When the clinical oncologist (operator) came to outline the PTV and OAR, she could not see sufficient detail to complete the task. This was annotated on the patient's record. The patient was rescanned using the large-field-of-view pelvic protocol, to improve the image quality, without further justification as one additional planning CT was permitted within the clinical protocol for optimisation purposes. A note was also added to the patient's record requesting the large-field-of-view pelvic protocol for CBCT use during treatment. The criteria for use of the large-field-of-view pelvic CT and CBCT protocols were subsequently amended to better identify which patients might benefit from these from the outset. The operator who reviewed the initial CT and requested the use and review of the large-pelvic-imaging protocols was completing the clinical evaluation and optimised the subsequent exposures by requesting use of the large-field settings.

9. Diagnostic and dose reference levels

Diagnostic reference levels (DRLs) are radiation dose levels, or administered activity, for typical diagnostic examinations on standard-size adults and children for broadly defined types of equipment [Regulation 2(1)].

Use of DRLs is not appropriate or required under IR(ME)R in therapeutic practice, but the use of dose reference levels for concomitant exposures is a useful tool in the optimisation process. Therefore, the principles of DRL use are outlined here and proposed as a method of demonstrating that optimisation has taken place for concomitant exposures in therapeutic practice.

In diagnostic imaging and interventional radiology, DRLs are used as a guide to promote optimisation and can help to identify issues relating to equipment or practice by highlighting unusually high or low radiation doses. DRLs are not expected to be consistently exceeded when good and normal practice is applied. They should be used in addition to professional judgement, and not used as dose limits or in comparison with an individual patient.

Regulation 6(5)(c) requires the employer to regularly review DRLs and make these available to operators. Local DRLs (LDRLs) should be set with regard to national and European DRLs where available, based on MPE advice [Regulation 14(3)(a)].

While European DRLs are available, national DRLs (NDRLs) better reflect UK practice. All UK DRLs are adopted and published through the process established by the Public Health England (PHE) NDRL Working Party.

NDRLs are set using data submitted by departments to national dose surveys. These national dose surveys or audits may be undertaken by PHE or by professional bodies.[56,57]

NDRLs for diagnostic nuclear medicine procedures are set by the Administration of Radioactive Substances Advisory Committee (ARSAC). These are the recommended administered activities for standard-size 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. LDRLs should be the subject of regular audits, comparing the median dose for a representative sample of patients in the department.

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

Dose reference levels are estimates of patient dose, usually given as dose indices that can be readily recorded from equipment (see Chapter 18), such as CTDI or dose length product (DLP). 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 has 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. 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.[58] Dose estimates for each standard type of exposure should be calculated locally, even if they fall below this threshold.

MRT is usually prescribed as a fixed activity or activity adjusted for body mass or surface area. Local protocols should specify a tolerance range on the activity to be administered.

Scenario 21

A department audits the dose recorded for 20 recent breast CT scans against NDRLs. They find that CTDI values are all within the DRL for this site, but that several of the patients have higher DLP values than the DRL. 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 DRLs.

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 clinical 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.

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 (Chapter 18), DRLs (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.

Recording of patient doses is also useful to assist with optimisation (for example re-treatment), audit of typical doses against local DRLs 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 practitioner of relevant parameters in order 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, on-treatment imaging and positional monitoring 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 or, where appropriate, have the capacity to transfer this information to the individual's record

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. 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 on-treatment imaging exposures is usually recorded in the OMS, so at the end of treatment, the operator can calculate the nominal total imaging dose.

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 so on, and dose reconstruction based on equipment log files or on-treatment imaging (for example 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 (for example to identify and compensate for anatomical changes).

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 can be challenging. Differences in disease burden and patient uptake result in wide variations in absorbed doses following the administration of a fixed activity. Determining absorbed dose following MRT can be complex and requires accurate 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. There are many resources available for guidance on MRT dose assessment and recording of appropriate data.[59–64]

Scenario 22

A child with relapsed leukaemia is to be treated in a clinical trial of an Yttrium^{90}-labelled monoclonal antibody as an alternative conditioning regimen to total body irradiation. In preparation for this, a series of four diagnostic SPECT-CT scans with the same antibody labelled with Indium^{111} is performed over five days to allow the likely dose to bone marrow (the target organ) and OAR to be calculated. The therapy will not proceed if the prior dosimetric evaluation is unfavourable.

11. Clinical evaluation

Regulation 12(9) requires the employer to ensure that a clinical evaluation of the outcome of all exposures must be 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. 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)].

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).

Treatment planning exposures

The clinical evaluation of planning exposures such as CT datasets is demonstrated by their use. The entire CT dataset should be used; that is, all slices should be reviewed as part of the planning process. The CT dataset used must be identifiable in the patient record. In practice, it is usually a specific operator involved in image fusion, delineation of target and OAR or plan production that takes responsibility for the evaluation of images used for treatment planning at the time of producing the plan. The operator should optimise the medical exposures for treatment planning, ensuring that the quality, extent and localisation of the medical exposure is appropriate for the purpose intended.

The exposures should follow the employer's procedures and any deviation should be recorded. Excessive artefact (for example artificial hip) may be a reason to consider images of insufficient quality for delineation and plan calculation. Audit of planning exposures that are deemed not to be fit for purpose should inform future processes and training needs. This should result in reduction of unnecessary exposures for future patients. This should be reflected in local procedures.

Treatment verification exposures

Verification of the intended treatment is performed by the operator and may require further medical exposures as per local protocol. 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 (for example the radiographer performing image matching). For these exposures, the quality of the image produced is a factor. These evaluations will provide the basis for adjustment or continuation of treatment and must therefore be carried out in a timely manner. This evaluation is documented by entitled operators as per the employer's procedure.

Scenario 23

A patient was planned for radical external beam radiotherapy for a lung tumour. Pretreatment verification exposures using CBCT showed the PTV was well covered, but the carina was in a different location by a factor of 10 mm in the AP direction. The images were discussed with the clinical oncologist (practitioner) and a decision made to perform CBCT for the first three fractions, which showed a consistent new position of the trachea and PTV coverage was very good, hence a replan was not required. Thereafter patient verification followed protocol with kV imaging. The image review together with the recording of the CBCT images fulfilled the requirements of clinical evaluation.

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'.[7] 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 entitled and adequately trained staff. 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. This should be reflected in local procedures and performed for all radiotherapy exposures. Appendix 8 provides a list of fields for consideration in an end-of-treatment summary letter.

Molecular radiotherapy

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 ^{131}I-mIBG therapy for neuroblastoma, or peptide receptor radionuclide therapy for a neuroendocrine cancer, an ^{123}I-mIBG scan with planar scintigraphy and SPECT-CT or a ^{68}Ga-DOTATATE PET-CT 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 ^{131}I-mIBG or ^{177}Lu-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 following review in an MDTM in the MDT minutes. An exception to this is ^{131}I ablation following surgery for differentiated thyroid cancer, where 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, for example, when an ^{90}Y-labelled radiopharmaceutical is used, as there is no gamma emission suitable for gamma camera imaging, although Bremsstrahlung imaging or PET imaging may be feasible. 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.

Scenario 24

A woman has undergone a total thyroidectomy and neck dissection for a papillary thyroid carcinoma with neck node metastases. She receives an ablative ^{131}I administration, 1.1GBq, 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 therapy administration reveals resolution of uptake in the neck as a result of the prior ablative administration, and uptake in the lung lesions. Later re-evaluation 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.

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.[65]

Correct identification (ID) of the patient is an operator task and must be undertaken prior to any exposure. Correct ID of the patient always starts with the referrer. All duty holders need to be appropriately entitled for this task. 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 (for example, 'What is your name?'). The procedure should state by whom the individual should be identified (for example 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. 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 (for example 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. 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	Things to consider
Patients lacking capacity to identify themselves	▪ Use hospital wristband to confirm ID ▪ Can the patient's relative or carer confirm their ID?
Patients with sensory impairment (eg, deaf or blind)	▪ Can ID be checked using written cards, braille or sign language to assist the active process? ▪ Could other forms of ID be used (eg, photo ID or driving licence)?
Individuals who speak an alternative language	▪ Local policy for the provision of a translation service ▪ Hospitals may require their own interpreter to be present and not just 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[66] (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 ancillary 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 (for example barcoding). Radiation incidents have occurred because the wrong electronic dataset or ancillary equipment has been used to plan or treat a patient.[67]

In MRT, similar principles apply, and procedures should specify how the correct radiopharmaceutical is identified, including labelling requirements. Further information on accidental and unintended exposures 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 breastfeeding and highlights some considerations for inclusion in the employer's procedure.

Table 13.1: Considerations for pregnancy and breastfeeding confirmation

Regulation	Things to consider
Procedure to establish pregnancy and breastfeeding status **Schedule 2(c)**	▪ Age range based on local demographics ▪ Timing and frequency of establishing pregnancy status ▪ Inclusion as part of the consent process ▪ Process if more than one operator is involved in an exposure ▪ Process for patients in theatres or under anaesthesia/sedation (eg, IORT or SIRT) ▪ Individuals lacking capacity ▪ Individuals with sensory impairment (eg, deaf) ▪ Individuals with insufficient command of English (or Welsh) ▪ Individual with variable-cycle menstrual periods ▪ Process to follow if pregnancy testing is part of establishing pregnancy status ▪ Process for the exposure of pregnant individuals ▪ Pregnancy disclosed in individuals aged under 16 (including support and safeguarding where appropriate*) ▪ Exceptions where pregnancy checking is not required
Measures to raise awareness **Regulation 6(8)**	▪ Posters in waiting areas ▪ Information in appointment letters and booklets ▪ Adequate training for those involved with patient communication

Regulation	Things to consider
Justification **Regulation 11**	▪ Consider alternatives 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 ▪ Optimised protocols for breastfeeding individuals ▪ Adequate operator training (how to adjust technique/protocols)

* 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.[68]

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 individuals in 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)].

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.[69]

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 11–55 years.

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

Scenario 25

A 15-year-old patient has been admitted for ^{131}I-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.

Theatres and patients under anaesthesia/sedation

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 provides further guidelines on preoperative enquiries.[70] The procedure may include the use of additional documentation such as the WHO checklist.[66]

Trans male or gender-nonconforming individuals

A trans person is someone whose gender differs from that assigned to them at birth. A trans male is a man who was assigned female at birth and therefore may have the capacity to become pregnant.

Consideration should be given to the employer's procedure to ensure it reflects the diversity of the gender spectrum in the population when making pregnancy enquiries. The employer's procedure should be in keeping with the wider trust/health board policy on patient dignity and privacy.[71] Tools such as information leaflets, posters and patient questionnaires can be used to facilitate effective communication. The Sex Identity Gender and Expression (SIGE) form may be adapted for use in the UK with minor modifications to some of the terminology; for example, 'Your doctor has referred you for treatment'. [72]

Where a referrer, practitioner or operator is unaware of the possibility of pregnancy due to the individual being unidentified/undeclared as a trans male or where the individual has not consented to the sharing of their gender identity or their childbearing potential, the individual to be exposed has the sole 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: Challenges and additional considerations when making pregnancy enquiries

Scenario	Additional things to consider
Referrer	▪ May not have asked the individual prior to referral, or has not provided the 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

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

Parent/guardian(s) present	▪ Individual unwilling or afraid to answer truthfully

Scenario	Additional things to consider
Underage sexual activity	▪ Legal consequences for those under 16 years (safeguarding process)
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	▪ Using tools such as the SIGE form

Practical application

The response to pregnancy enquiries should 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, local procedures for unknown pregnancy status should be followed. The operator should inform the practitioner, who may reconsider justification.

Individuals should be asked whether they might be pregnant. They are likely to respond with 'No', 'Yes' or 'Not sure'. Table 13.3 includes possible actions to take following each response.

Table 13.3: Possible actions to consider

Response	Possible action
No	▪ Document and proceed with the exposure
Yes	▪ Document response and action ▪ Consider deferring the treatment if not urgent ▪ Operator to discuss the exposure with a practitioner and the MPE to decide how the exposure could be further optimised, taking into consideration the potential exposure of the fetus ▪ Involve patient in discussions ▪ Confirm if the exposure is still justified and discuss with the practitioner if it can be deferred

Response	Possible action
Not sure	▪ Determine whether the individual's period is overdue ▪ Consider deferring the exposure if not urgent ▪ If their period is overdue, or they report a missed period, they should be considered pregnant[73] ▪ Consider the use of an appropriate pregnancy test, taking into account the risk to the fetus; the individual must consent to pregnancy testing ▪ 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[74]

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.

It is good practice to ensure that individuals have the time, opportunity, privacy and safety to raise the possibility of pregnancy with the referrer, practitioner or operator. Practitioners and operators must be adequately trained to be able to explain the benefit and risk of the exposure. 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.

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.

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 accidental or unintended exposures. If an unintended fetal exposure occurs, this may require notification to the relevant enforcing authority in accordance with published guidance.[75]

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.[35] Where guidance is not available from ARSAC, other recommendations are available, such as for SIRT.[76]

Breastfeeding

Breastfeeding is completely contraindicated for MRT using radionuclides that are excreted in breast milk.[35]

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 consultant 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.[35] Recommendations for specific treatments are also available, such as for thyroid cancer.[77]

14. Communicating benefits and risks and patient information

Communicating benefits and risks

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. The introduction of Schedule 2(i), requiring an employer's procedure for providing adequate information relating to the benefits and risk associated with the exposure, formalises 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 risk 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.[78] 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.

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.[79–82] As such 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.

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.[83,84] Table 14.1 lists examples of different communication methods and things to consider when establishing an employer's procedure.

Table 14.1: Examples of different communication methods when establishing an employer's procedure

Type of communication	Things to consider
Verbal discussion	▪ Staff training ▪ Use of standard phrases to ensure a consistent message ▪ Patient dignity when deciding a location for discussions ▪ Sufficient time for questions ▪ Availability of additional advice (eg, MPE)
Written consent	▪ Following verbal discussion on benefits and risks
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 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.

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 IT system, 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
Additional advice is required	▪ Contact details for support (eg, MPE or nuclear medicine physician)
Patients lacking capacity	▪ Information provided to representative
Patients with sensory impairment	▪ Additional tools
Individuals who speak alternative languages	▪ Information leaflets in different languages/interpreter
Carers and comforters	▪ Non-standard situations where additional written information will be required

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 IRR2017 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 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.[85] 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 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.[86,87] 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.[88] 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 is only around 1,500 cases per year in the UK[88]
- The majority of childhood cancers do not require radiotherapy, meaning that paediatric radiotherapy comprises less than 1% of all radiotherapy[89]
- Children usually have a very diverse spectrum of malignancies, with a different range of tumour types compared with adults, meaning that there are very few patients in each subcategory treated at each department
- 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 three or four years of age, or older if there are learning 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.

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 European Paediatric Soft Tissue Sarcoma Group's Frontline and Relapsed Rhabdomyosarcoma Trial[90]
- The Second International Inter-Group Study for Classical Hodgkin Lymphoma in Children and Adolescents.[91]

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.

Table 15.1: Considerations when optimising paediatric exposures

Requirements	Things to consider
Attention to optimisation of paediatric exposures Regulation 12(8)	▪ Effective immobilisation ▪ Appropriate imaging protocols for a range of ages/sizes ▪ Target volumes individually planned ▪ Doses to OAR kept ALARP ▪ Peer review of volume delineation[92] ▪ Delivery appropriately verified ▪ Weight-adjusted administered activity
Adequate training Regulation 17(1)	▪ Specialist training programmes for operators and practitioners

Requirements	Things to consider
Co-operation with other specialists involved Regulation 10(6)	▪ Multiprofessional support and advice ▪ Sharing of relevant information ▪ MDTMs
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.[92] 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.[55,93,94]

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 radiation therapy (IMRT). An example is clinical mark-up with an applied orthovoltage field for a painful bone lesion.

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.[55] 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 Ionising Radiations Regulations 2017.[95]

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. 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. 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.[96,97]

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.

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

Criteria	Examples
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 ^{131}I who is unable to follow standard instructions to sleep apart for a period of time

Scenario 26

A patient attends the nuclear medicine department for ^{131}I treatment of benign thyroid disease with their partner. The patient is anxious and asks for their partner to accompany them during the administration for additional reassurance and support. Members of the public are not permitted to be present in the room while the administration is taking place, but they may be present for pretreatment discussions. Following these discussions, the patient and their partner confirm that they can comply with the radiation protection precautions and the patient no longer requires the support of their partner during the administration. As the partner is not present in the room during the administration and they can comply with the standard precautions, they do not need to be designated as a carer and comforter. The partner will receive an exposure, but for radiation protection purposes they are considered to be a member of the public.

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.[98] 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.

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.

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
Individual justification Regulation 11(1)(b)	▪ Benefits and risks from the exposure to the carer and comforter ▪ Use of authorisation guidelines ▪ Criteria for individual justification by practitioner ▪ Provision of training to practitioners and operators

Regulatory requirement	Things to consider
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
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, describes the role of the MPE and states 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 2D and 3D 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.[99,100] 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. 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 (for example ^{131}I 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 IRR17), 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.[38,39] They should normally be a clinical scientist with appropriate post-registration experience, specialising in radiotherapy physics. Although the regulations allow for a group of individuals to fulfil this role (an MPE body), this is not recommended in radiotherapy, because individual responsibility should be taken for each MPE's involvement.

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. 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. However, more detailed division is not recommended, since all MPEs should be involved in the four areas described above: equipment management, dosimetry, optimisation and regulatory compliance. 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 some of the roles of an MPE

Area	Example roles
Equipment management	▪ Advise on selection and use of all radiotherapy equipment, and contribute to preparation of technical specifications for equipment and installation design ▪ Be responsible for acceptance testing and commissioning of new equipment or techniques, including selection of appropriate test equipment ▪ Be responsible for the definition and management of QA of equipment, including corrective action to be taken when tolerances are exceeded ▪ Be responsible for the technical management of clinical computing software and systems, in collaboration with hospital IT staff
Dosimetry	▪ Be responsible for absolute dosimetry of treatment equipment, including definitive calibration, management and calibration of dosimetry equipment ▪ Be responsible for physical measurements for the evaluation of dose delivered, including pretreatment (phantom-based measurements) and on-treatment (*in vivo* dosimetry)
Optimisation	▪ 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

Area	Example roles
Optimisation (contd)	▪ 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
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, accidental or unintended exposures, including reconstruction of dose delivered ▪ Contribute to the training of practitioners 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 authorising 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.

Scenario 27

A new linac is installed in the department. Before any commissioning, the critical examination is performed by the RPA, along with dose surveys to establish the sufficiency of shielding and calculations of predicted environmental dose rates (to staff and public). The MPE takes responsibility for subsequent acceptance and commissioning of the unit, including the accuracy of dosimetric data used by the planning system, such as leakage and scatter within the treatment room that will affect doses to patients.

18. Equipment and quality assurance

Regulatory requirements for medical radiological equipment were previously divided between IRR99 and IR(ME)R 2000.[3,101,102] The equipment requirements in IRR2017 were revoked when IR(ME)R 2017 and IR(ME)R (NI) 2018 came into force.

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 that 'delivers' ionising radiation to a person undergoing an exposure or 'directly controls or influences' the extent of the exposure and hence the dose delivered [Regulation 2].

Examples of equipment delivering ionising radiation within radiotherapy departments include:

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

Examples of ancillary equipment that influence 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
- MRI scanners if used directly for treatment planning without a corresponding planning CT scan
- Dose calibrators, calculation software and any imaging equipment (for example gamma cameras) used in MRT to determine the dose delivered
- Dose rate monitors used for patient monitoring before leaving the hospital.

Local procedures and workflow will determine whether such ancillary equipment directly influences the dose received by an individual and therefore whether it meets the IR(ME)R definition.

The definition of equipment extends to all new or secondhand 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 (for example off-site IORT or brachytherapy).

Scenario 28

There are many examples of how equipment that does not deliver ionising radiation can still influence dose. Some are included below:

- Where department A has introduced bladder scanning with ultrasound into its routine prostate planning, the bladder scanner directly influences whether an individual receives an exposure and potentially the extent of the exposure
- Bladder scanner used to determine the volume of bladder at each treatment fraction and hence the plan of the day in the case of adaptive RT
- Direct planning on MRI scan without a corresponding CT scan – while the MR does not directly expose the patient to ionising radiation, it does determine the extent and position of the planned target volume
- Dose calibrator used for measuring activity of an isotope such as ^{233}Ra.

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	▪ Include all ancillary equipment ▪ Remove any equipment no longer in use
Carry out testing of equipment prior to use for any medical purpose	▪ Programme for acceptance testing

Equipment duties on the employer	Things to consider
Carry out regular performance testing	▪ 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	▪ Procedure for informing and co-ordinating testing with medical physics team ▪ Handover arrangements
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	▪ Record QA results ▪ Define 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	▪ MPE involvement in specification for any interventional radiology (eg, SIRT) and CT equipment

Equipment inventory

A department must maintain an up-to-date inventory of equipment, including ancillary devices that can directly control or influence the exposure, which 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.

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. Consideration could be given to making some of this information, for example age of equipment, available to the public upon request.

For the majority of equipment, creating and maintaining such an inventory is straightforward. However, treatment planning and delivery systems rely heavily on software applications, and a list of current software versions for each element should also be included within the inventory or kept within a separate but accessible document. Imaging systems attached to linear accelerators may have their own serial number and, if so, 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.

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 ^{131}I capsules, but also for ensuring the appropriate activity is drawn up for injecting radioisotopes, such as ^{223}Ra, used for the treatment of bony 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 can also 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.

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)[103] ▪ 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

Programme	Things to consider
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

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.[104–106]

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 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.

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 [Regulation15(4)]. Special attention should be given to the accuracy of dose estimates and there should be systems of work to optimise exposures (for example to minimise exposure time) where these are used (for example 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 CDTIvol 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 CDTIvol 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.

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 (for example 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 (for example a fleet of linacs) or monitors a single piece of radiation equipment (for example as the record and verify system does on some individual treatment devices). For standalone units especially, appropriate resilience should be established for backup 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: ▪ Procurement phase of equipment selection ▪ Assessment of dose optimisation features on imaging equipment ▪ Choosing the most appropriate equipment to meet the service requirements

Stages of equipment life cycle	Things to consider
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

Accidental or unintended exposures

IR(ME)R defines the terms accidental exposure and unintended exposure in Regulation 2. These apply to radiation incidents that involve both equipment and procedural failure. The regulations require the employer to provide a system for analysis, recording and notifying of accidental or unintended exposures [Regulation 8(3)]. IR(ME)R differentiates between significant accidental or unintended exposures (SAUE) and clinically significant accidental or unintended exposures (CSAUE).

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 regulations require that SAUE are notified to the relevant enforcing authorities. The relevant enforcing authorities have published joint guidance on notification thresholds and requirements for SAUE.[75] At the time of producing this document, the SAUE guidance requires all CSAUE to be notified to the relevant authority. While CSAUE are included within the criteria for SAUE, not all SAUE will be clinically significant.

Clinically significant accidental or unintended exposures

The DHSC IR(ME)R guidance does not define CSAUE.[7] The DHSC has tasked the clinical and medical professional bodies in collaboration with the health departments to provide further guidance on this topic. This guidance aims to fulfil this request.

The requirements of the regulations are consistent with duty of candour and the need to conduct clinical practice in an open and transparent manner.[107–109] The definition of moderate harm required to trigger the duty of candour has been used as the basis for the following guidance.[110]

The National Reporting and Learning System (NRLS) (now part of NHS Improvement (NHSI)) defines events that cause moderate harm as:

> *Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.*[110]

Justified exposures that are delivered as intended are not CSAUE, even where these exposures 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.

For the purposes of this guidance a CSAUE in radiotherapy is defined to be one that has had, or is expected to have, a measurable effect on the patient's tumour control,

normal tissue toxicity or quality of life. In addition, a CSAUE is any other situation where a patient has been exposed to ionising radiation that, in the judgement of the practitioner, is significantly greater than those generally considered to be proportionate in the circumstances.

The medical opinion of the multiprofessional healthcare team should be taken into account when considering effects that may be physical or psychological. Effects may be acute, and require a change in management or additional interventions, or they may cause a significant increase in long-term risks.

It is the responsibility of the practitioner to determine whether an accidental or unintended exposure is clinically significant using a risk-based assessment with due consideration to the dosimetric information provided by the MPE, patient factors, potential toxicity and tumour control factors. 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. Considerations for what constitutes a CSAUE are described in Table 19.1.

Table 19.1: Example considerations for CSAUE determination

These situations will often be CSAUE, but the practitioner and MDT should review each case individually to determine if the accidental or unintended exposure is clinically significant.

1	All total geographical misses of a therapy exposure, including if for a single fraction of prescription Examples include setting up to the wrong reference marks in external beam radiotherapy or extravasation in MRT
2	When the delivered dose to the planned treatment volume is 1.1 times (whole course) or 1.2 times (any fraction) the intended dose
3	When the delivered dose to the OAR is 1.1 times the tolerance dose as specified locally for that organ for a whole course of treatment
4	When the delivered dose to the planned treatment volume is 0.9 times less the intended dose (whole course) in external beam radiotherapy or brachytherapy When the administered activity is less than 0.9 times the prescribed activity ±10% in MRT[111]
5	When there is an unintended clinical impact or compromise in the effectiveness of treatment, regardless of dose due to errors in scheduling the treatment or otherwise (eg, patient referred for breast and nodal treatment, treatment delivered to breast only)

6	Unintended fetal exposure resulting in a 0.1% (1 in 1,000) or greater risk of radiation-induced childhood cancer. This equates to >10 mGy to the fetus in most circumstances.[112] In the context of this document, this unintended dose level should only be used as a trigger for further investigation, rather than any specific intervention (eg, termination) that will depend on the outcome of that investigation.
7	Extravasation of radiopharmaceuticals resulting in skin doses above 5 Gy[49]
8	Failure to follow thyroid-blocking procedure resulting in an unintended dose to the thyroid of more than 50 mGy from administered radiopharmaceuticals[35]

Employer's procedure for CSAUE

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

Good practice will include the requirements of Schedule 2(l) within a comprehensive radiotherapy error reporting procedure. Table 19.2 includes things to consider for inclusion within a comprehensive employer's procedure.

Table 19.2: Employer's procedure for local radiation incident reporting, investigation and external notification

Area	Things to consider
Preliminary investigation process	▪ How duty holders identify error and timelines for local reporting ▪ Mechanism for local reporting ▪ Specify information required to determine what happened, where and when it happened and the staff involved ▪ Immediate action to ensure the event is not repeated (eg, equipment taken out of service) ▪ 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,[75] CSAUE definition) ▪ Identify responsible person for notifying the relevant enforcing authority (where required)

Area	Things to consider
Detailed investigation process	▪ Identify causes and contributory factors ▪ Remedial action to prevent or minimise similar failure affecting others ▪ MPE to calculate dose delivered in error ▪ Establish if any others may be similarly affected ▪ Trend analysis and comparison with other similar errors[67,113] ▪ Systems analysis, effectiveness of current safety barriers[24,114] ▪ Report on what actually happened and compare with what should have happened
CSAUE	▪ Estimation of dose delivered and risk to individual exposed ▪ Involvement of the practitioner, MPE and local care team ▪ Informing the individual exposed or their representative, the referrer and practitioner
Informing the individual exposed/ representative, referrer and practitioner	▪ Identify responsible person for informing the individual exposed or their representative, usually the clinical oncologist or nuclear medicine physician ▪ Record of information provided, and discussions held ▪ Record of a decision not to inform the individual exposed, including detailed justification
Analysis of events	▪ Coding and classification of radiation incidents or errors[24,114] ▪ Systematic analysis of radiation incidents or errors, to facilitate a safety culture[67,113] ▪ Lessons learnt, including areas that require review and improvement, informing changes to practice ▪ Communicate and share learning themes to all stakeholders within the organisation

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.

Further detailed guidance is available on dealing with the consequences of significant radiotherapy errors and offering support to the patient.[24] Employers may need to consider appropriate 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.

Regulation 8(4) sets out the process the employer must follow when it is believed that an accidental or unintended exposure has or may have occurred:

- Carry out a preliminary investigation
- Immediately notify the relevant enforcing authority in accordance with SAUE guidance[75]
- 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 radiation incidents should be notified to them along with appropriate timescales for notification.[75] Notifications to the relevant enforcing authority should include contact details of an individual who can provide further information as required. Such an individual should have a senior position in the department involved, to ensure the correct information is made available. 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 The 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 malfunction, other enforcing authorities should be notified; for example, the Medicines and Healthcare Products Regulatory Agency (MHRA) in England and Wales, Health Facilities Scotland in Scotland and the Northern Ireland Adverse Incident Centre in Northern Ireland.

The process of investigation should be standardised.[115] It is important that everyone involved in the analysis, reporting and notification of accidental or unintended exposures understands the value of the process and actively contributes so that learning can be shared and patient safety is improved.[116]

All radiotherapy providers should have documentation in place that clearly sets out local reporting criteria for accidental or unintended exposures and demonstrates due consideration to the SAUE guidance and Table 19.1.[75] The MPE must contribute to radiation incident analysis [Regulation 14(3)(f)]. 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 errors and near misses.

The fundamental role of reporting and learning systems is to enhance patient safety by learning from failures of the healthcare system.[117] Most problems are not just a series of random, unconnected, one-off events. They are triggered by poor systems and often have common root causes, which can be grouped together thematically and addressed.

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. Experience has shown that as an organisation's reporting culture matures, staff become more likely to report radiation incidents. There is an emerging evidence base that organisations with a higher rate of reporting have a stronger safety culture.[118] All radiotherapy departments should have clear guidelines in their quality system on error management, and actions to be taken when errors occur. Guidance for coding and classification of errors and near misses is available.[24,114]

Documentation relating to errors and near misses should be retained in line with relevant guidance.[119] Clinical departments should have a forum that includes a record of errors and near misses and is available for all staff to review to ensure best practice is maintained, by sharing lessons learnt with all staff locally and applying lessons learnt to mitigate these events.

Participation in the national voluntary reporting and learning scheme is indicative of an open and transparent safety culture.[67,113,120] 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.

Radiotherapy departments have well-established local reporting and learning systems in place for the recording, investigation, escalation, analysis and learning from radiation incidents and near misses. Regulation 8(3) mandates this practice.

Outputs from radiation incident analysis should be used to inform prospective risk assessments in thematic areas identified in the analysis as part of a study of the risk of accidental and unintended exposures.

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 accidental or unintended exposures.

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 unintended or accidental exposures. A working example from a radiotherapy department is provided in Appendix 9.

The European Commission 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, or a proactive risk assessment, is a 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 preventive measures in place within the service. To understand how these risk assessment methods are applied in radiotherapy, besides general concepts of risk (for example 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 or equipment failures and human errors, and useful for identifying safety barriers that can be implemented to limit the consequences of failures and errors.[17] Reactive analysis of events focuses on the study of a specific event, and involves the investigation of causes, identification of safety barriers that failed and the corrective measures required. This type of analysis should be used to update proactive risk assessments.[17]

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 reporting and 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.[67,121–125]

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 radiotherapy errors or near misses.

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 annual safety events that cover a standard agenda, including proactive and reactive risk assessments and learning from radiation incidents. The risk assessment programme needs to be encouraged, resourced and supported by management as part of an effective safety culture.

Safety culture

Staff are more likely to report errors or near misses where there is an open, blame-free reporting culture and where the clear aim of reporting is to learn and to improve patient safety. 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 learnt to mitigate these events in future.

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

As part of a well-established safety culture, UK radiotherapy departments employ a number of measures to minimise the magnitude and probability of accidental and unintended exposures. These include:

- Requirement for professional registration of staff and codes of conduct
- Requirements for training and CPD
- Requirement for QMS
- Well-established local and national radiation incident learning systems
- Regional dosimetry audits
- Culture of MDT working
- Availability of professional and national guidance on service delivery
- Independent and peer review.

Table 19.3: Employer's procedure to reduce the probability and magnitude of accidental or unintended exposures

Area	Things to consider
Optimisation	▪ Use of NDRLs for CT planning exposures where appropriate (and CBCT once available)[56,57] ▪ Adoption of national image-guided radiation therapy (IGRT) protocols[126] ▪ Adoption of national treatment prescriptions where appropriate[51] ▪ Delivery of therapeutic exposures appropriately verified ▪ MPE involvement ▪ See Table 8.2
Governance	▪ Establishment of radiation protection and/or medical exposure committees

Area	Things to consider
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] ▪ Audit of all parts of the clinical pathway ▪ Monitoring 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 complete
Entitlement	▪ Effective entitlement process with up-to-date scope of practice for individual duty holders
Error and near miss analysis	▪ Analysis of trends to identify need for change in practice or procedure or need for further training ▪ 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.[36,35] 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.

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.

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.[35]

Scenario 29

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.[35]

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 ^{177}Lu DOTATATE treatment. Certain conditions need to be met prior to administration of the medicine:

- The POM is administered by an operator in accordance with the protocol
- The exposure is authorised by a practitioner or an operator following authorisation guidelines
- The practitioner holds a licence for the administration of the radioactive substance
- The POM is not a product subject to special medical prescription
- The administration of the POM is included in 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 examples of the requirements and things to consider when carrying out research exposures.

Table 21.1: Requirements for research exposures

Regulation	Requirements
Licensing Regulations 5 and 11(1)(a)	▪ Appropriate employer and practitioner licences must be in place prior to commencing research trials involving the administration of radioactive substances
Regulation 6(5)(d)(i)	▪ Dose constraints must be in place for individuals taking part in research trials where no direct medical benefit is expected
Justification Regulation11(1)(d)	▪ All research trials must be approved by a recognised REC before commencing ▪ All research trials involving the administration of radioactive substances must be approved by an expert committee (ARSAC)
Optimisation Regulation 12(4)	▪ Individuals concerned must participate voluntarily ▪ Individuals must be told in advance about the risks of the exposures ▪ Dose constraints must be adhered to ▪ Individual target levels of dose must be planned where the participants 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 lists the requirements under the regulations and gives some examples of how the written procedure could describe how they may be addressed in practice.

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

Requirement	Things to include in the employer's procedure
Practitioner and employer licences	▪ Process to ensure that appropriate licences are held to cover all administrations of radioactive substances required by the research trial
Individuals participate voluntarily	▪ 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[130] from the Health Research Authority (HRA)

Dose constraints or dose targets	▪ Description of how a dose constraint or a dose target is set for each research trial:
	  ▪ Dose constraints must be established for all research trials involving *standard* procedures, and this approach should be adopted for concomitant exposures
	  ▪ Dose targets must be established where direct patient benefit is expected (eg, experimental therapeutic practices)

Setting a dose constraint	▪ Description of how the local dose constraint is set:
	  ▪ When the research protocol and the total research protocol dose (TRPD) has been centrally reviewed and calculated (eg, through the HRA radiations assurance process), there may be situations where it is not appropriate to use the TRPD as the local dose constraint
	  ▪ Local dose constraints should be optimised and take into consideration reasonable variations in local practice (eg, available equipment)

Dose constraints are adhered to	▪ Periodic dose audits, if applicable
Setting dose targets	▪ Description of how local dose targets are set and whether these are set at a trial or individual level

The HRA defines exposures to ionising radiation as 'research exposures' where both the following criteria are met:[131]

a. The exposure is required as an integral part of, and for the purpose of, the research. This specifically includes:
    i. Exposures undertaken prospectively to confirm the eligibility of potential participants in the research trial and/or to provide (qualitative or quantitative) data regarding disease status at baseline; and/or
    ii. Radiotherapy as part of a treatment strategy to which patients are assigned prospectively by the protocol, either as part of an experimental or control arm, and which will be evaluated by the research trial; and/or
    iii. Exposures undertaken at formal time points within the research protocol schedule to assess disease status or response to treatment; and/or
    iv. Exposures where there are clear requirements as to how they should be conducted, for example machinery to be used, imaging slice thickness; and/or
    v. Image-guided procedures undertaken while the patient is enrolled in the research trial
b. Consent for the exposure is sought from potential participants as part of their consent to take part in the research (including screening for eligibility).

Exposures that meet these criteria are considered to be research exposures, even where they are part of normal clinical care and there are no 'additional' exposures. Exposures that are mandated by the protocol and would be additional to the standard of care should be identified and a dose constraint applied. Information relating to standard of care and additional exposures should be available in the approved study documentation. A local review process should ensure that the study documentation is satisfactory and that the local centre can comply with the dose and risk estimations made in the approved study documentation.

Further guidance and a number of typical examples are available from the HRA to aid in determining whether a research trial includes research exposures.[131]

Scenario 30

A clinical trial seeks to treat patients with advanced cancer with a novel agent. Median survival is expected to be less than 12 months. The protocol mentions that, in addition to concomitant medications, palliative radiotherapy may be given to patients with bone metastases in line with clinical need and local practice. Giving radiotherapy will not affect the primary outcome of the study.

This is *not* a research exposure. Although the protocol mentions the possibility of radiotherapy being administered to patients in the study, the radiotherapy is not required by the study and will not affect the study outcomes. Patients receiving radiotherapy will not be studied as a separate arm of the design. Delivery of radiotherapy is entirely dependent on clinical need, not the requirements of the research. Consent to undergo radiotherapy is not sought as part of the consent to take part in the study.

Scenario 31

A clinical trial to treat patients with relapsed or refractory leukaemia uses a novel radiopharmaceutical investigational medicinal product (IMP) ^{90}Y labelled monoclonal antibody to condition the bone marrow prior to stem cell transplant. ^{111}In-labelled monoclonal antibody is also an IMP and is used for a series of diagnostic imaging scans prior to therapy administration. These scans allow dosimetry calculations to be conducted to confirm absorbed doses fall within the required limits.

Both administrations as part of this trial *are* research exposures as the exposures are an integral part of the research. Consent to receive the radiopharmaceuticals must be sought as part of the trial consent. In addition, employer and practitioner licences must be obtained for the use of both radiopharmaceuticals

Approval and authorisation

Ethics committee approval

Before any research involving exposures to ionising radiation can go ahead, the research study must be approved by a REC. Further detailed guidance is available from the HRA on how to apply for REC approval.[131] This guidance includes a number of typical examples where questions could arise about whether the trial involves research exposures.

ARSAC approval

Research involving the administration of sealed or unsealed radioactive substances will require approval from ARSAC. Research sponsors are responsible for obtaining ARSAC approval. Detailed information on this process can be found on the ARSAC website.[35] ARSAC research approvals will specify the approved procedures in the study. Ethics committee and ARSAC approval does not automatically mean that all the research exposures included in the study have been justified and authorised on an individual level. These are separate activities. The practitioner may take into account the ethical considerations in regard to the study population, but the individual characteristics of each patient must also be considered.

Licensing

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.[35]

Practical considerations

IR(ME)R requires employer's procedures to provide safeguards for medical and biomedical research trials. It is important that radiotherapy and nuclear medicine staff can identify those exposures that are required for research purposes. This can be achieved in several ways; for example, using a specific study code on the referral, or annotated on the patient treatment chart. These processes should be described in the employer's procedures.

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 all research exposures as appropriate
- The number, type and timings of required exposures.

It may be helpful to consider having a radiotherapy or nuclear medicine 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 ethics committee and ARSAC, and relevant employer and practitioner licence information.

While the exposures in the whole study will have been approved by the REC, HRA and ARSAC, and contain information approved by a lead MPE and clinical radiology 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.

Regular communication between the radiotherapy department and/or the nuclear medicine department and the research team is encouraged.

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130. Health Research Authority. *Generic risk statements regarding ionising radiation for MPE and CRE statements in the IRAS application form and participant information sheets.* London: Health Research Authority, 2017.
131. www.myresearchproject.org.uk/help/hlpradiation.aspx#Research-exposure-examples (last accessed 22/5/20)

Appendix 1. Glossary

Term	Definition
Adequate training	Training that satisfies the requirements of IR(ME)R Schedule 3 (see Chapter 4).
Authorisation	The record 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	An individual who is 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 HCPC.

Term	Definition
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 had or is expected to have a measurable effect on 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, verification and repeat exposures.
Continuous 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).
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).

Term	Definition
External beam radiotherapy	Where the 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 radiopharmaceuticals 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.

Term	Definition
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 ALARP, in keeping with the therapeutic purpose (see Chapter 8).
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; QC is a part of QA (see Chapter 3).

Term	Definition
Quality control (QC)	The set of operations (programming, co-ordinating, implementing) intended to maintain or to improve quality; 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 HCPC. 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 error	A nonconformance where there is an unintended divergence between an exposure delivered or process followed and that defined by local protocol. This includes events that lead to radiation incidents that might be minor, SAUE, CSAUE or near misses (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 and chiropractors. Examples of professional body regulators are General Medical Council, General Dental Council, HCPC.

Term	Definition
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.
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 used in this document

Abbreviations	Definition
AHCS	Academy for Healthcare Science
ALARP	As low as reasonably practicable
ARSAC	Administration of Radioactive Substances Advisory Committee
AXREM	Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care
CBCT	Cone beam computed tomography
CCT	Certificate of Completion of Specialist Training
CoR	College of Radiographers
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
FRCR	Fellowship of the Royal College of Radiologists
GMC	General Medical Council
GTV	Gross tumour volume
HCPC	Health and Care Professions Council
HRA	Health Research Authority
IMP	Investigational medicinal product

Abbreviations	Definition
IORT	Intraoperative radiation therapy
IPEM	Institute of Physics and Engineering in Medicine
MRT	Molecular radiotherapy
NICE	National Institute for Health and Care Excellence
NRLS	National Reporting and Learning System
OAR	Organ at risk
OMS	Oncology management system
PET-CT	Positron emission tomography/computed tomography
PIS	Participant information sheet
POM	Prescription-only medicine
PTV	Planning target volume
QMS	Quality management system
RCR	Royal College of Radiologists
REC	Research ethics committee
RPA/RPS/RWA	Radiation protection adviser/radiation protection supervisor/ radioactive waste adviser
RTE	Radiotherapy errors that include near misses
SAUE	Significant accidental or unintended exposure
SCoR	Society and College of Radiographers

Abbreviations	Definition
SBRT/SABR	Stereotactic body radiation therapy/Stereotactic ablative radiotherapy
SIRT	Selective internal radiotherapy
SPECT	Single photon emission computed tomography
SUV	Standardised uptake values
TPS	Treatment planning system
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

Not legally required for radiotherapy exposures. In the absence of a written procedure a statement is required that these exposures are not undertaken. However, departments may have a written procedure in place for dose reference levels used for CT planning scans and CBCT, to evidence optimisation for these types of exposures. The following might be considered:

- What dose reference levels are in place?
- Where can they be found? (eg, displayed in control areas or included within the exposure chart)
- 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)

j) Recording of a clinical evaluation

- Consider the type of clinical evaluation for planning, verification and treatment.
- Where is clinical evaluation recorded?
- Who records the clinical evaluation?
- What exposure factors should be included in the clinical evaluation?
- How is training provided to staff carrying out and recording clinical evaluation?
- How is the operator carrying out this task identified?
- How and when are audits carried out to assess compliance with employer's procedures?

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

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.
- Use of NDRLs for CT planning exposures where appropriate.
- Adoption of national IGRT protocols.[119]
- Adoption of national treatment prescriptions where appropriate.[49]
- 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.[99]
- 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 clinically significant unintended or accidental exposures

- 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.

Appendix 4. Criteria for clinical protocols

Fields to consider when establishing protocol templates.

Field	Areas to consider/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 risk ▪ 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)

Field	Areas to consider/examples
CTV	▪ For example, CTV6600 = primary tumour and involved high-risk nodes with at least a 10 mm margin
PTV	▪ For example, PTV = CTV +3 mm
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 ▪ See Appendix 8
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 5a. Example of a clinical protocol

Regulation 6(4) requires the employer to have in place written protocols for every type of standard radiological practice. The following provides an example of a thoracic oncology clinical protocol. 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.

Thoracic oncology radical radiotherapy protocol

Indication

- Non-small cell lung cancer
- Primary treatment or postoperative
- Radical intent[1,2]

Referral guidelines

- Stage IA to IIIB based on CT scan of chest/abdomen, PET scan
- Any non-small cell pathology
- Performance status – ECOG 0–3
- No contraindications for radiotherapy

Chemotherapy

- Neoadjuvant, or concurrent as per lung cancer chemotherapy guidelines (see Appendix A)

Clinical trials

- Details of clinical trials are included in Appendix A

Information for patients

- Local patient information sheet
- Patient consented with information on individualised benefits and toxicities2,3

Consent

- Patients consented with individualised information of planned treatment
- Booking form consent completed

Planning technique

- Planning CT scan with slice thickness of 2 mm covering neck and whole thoracic cavity
- Patient in supine position using beam directional shell (BDS) immobilisation or wing board with knee rest
- IV contrast as requested by practitioner
- 4D-CT scan as requested by practitioner
- Scanning will be as per departmental documentation

Target delineation

- Primary treatment
  - GTV – outlining of gross demonstrable primary tumour and involved nodal disease

  - GTVs are outlined according to the departmental outlining guidelines based on international consensus guidelines using diagnostic CT scan and PET scan
  - GITV – generated using 4DCT
- Postoperative
  - No GTV
  - CTV of involved or suspicious margin
- GTV/GITV to CTV/CITV margin: consider 5 mm–8 mm in all directions concentrically
- CITV to PTV margin: 8–12 mm all directions concentrically
- CTV to PTV: 10 mm lateral + 15 mm superior and inferior direction

Dose and fractionation

- 54 Gy in 36#: CHART
- 55 Gy in 20# or 60 Gy in 30#
- 39 Gy in 13# with cord shielding last two fractions
- 36 Gy in 12#

Treatment planning and critical organs

- See Appendix A for relevant quality documents
- OAR contouring and doses as per national and international guidelines[3]

Pretreatment/treatment verification

- Pre-verification CBCT imaging
- Verification imaging as per imaging protocol

On-treatment review

- Patients reviewed weekly for radiotherapy toxicities; after completion of treatment patients are seen in outpatient clinic for regular medical review

Treatment letter

- On completion of treatment a summary of the radiotherapy dose and toxicities experienced are documented
- In addition, expected acute and late side-effects are detailed with recommended treatments

Evidence base

1 [Reference 1]

2 [Reference 2]

3 [Reference 3]

Appendix 5b. Example of a clinical protocol

Regulation 6(4) requires the employer to have in place written protocols for every type of standard radiological practice. The following provides an example of a thyroid oncology clinical protocol. 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.

Radioiodine remnant ablation (RRA) and radioiodine therapy (RAIT)

Introduction

Following a total or near total thyroidectomy, some ^{131}I uptake is usually demonstrable in the thyroid bed. ^{131}I-induced destruction of this residual thyroid tissue is known as radioiodine remnant ablation (RRA). Radioiodine therapy (RAIT) refers to administration of ^{131}I with the intention to treat residual, recurrent or metastatic disease.

^{131}Iodine sodium iodide – physical properties

- Half-life: 8 days
- Beta energy: 606 KeV
- Gamma energy: 364 KeV
- Tissue penetration: 0.6–2 mm

Referral guidelines/indications for RRA/RAIT [BTA Guidelines – 2014]

No indications – all criteria below should be met ▪ Tumour ≤1 cm unifocal or multifocal ▪ Histology classical papillary or follicular variant of papillary carcinoma, or follicular carcinoma ▪ Minimally invasive without vascular invasion ▪ No invasion of thyroid capsule (extra thyroidal extension)	**RRA not recommended**
Definite indications – any one of the criteria below should be met ▪ Tumour >4 cm ▪ Any tumour size with gross extra thyroidal extension ▪ Distant metastases present	**RRA recommended**
Uncertain indications – all other cases Conflicting or inadequate evidence does not allow recommendations to be made for or against RRA. One or more of the following risk factors may identify patients at a higher risk of recurrence who may benefit from RRA:	**Selective use of RRA**

- Extension of tumour beyond thyroid capsule
- Widely invasive follicular thyroid cancer
- Unfavourable cell type (tall cell, columnar or diffuse sclerosing papillary cancer, insular or poorly differentiated cancer)
- Multiple lymph node involvement, large size of involved lymph nodes, high ratio of positive to negative nodes, extracapsular (nodal) spread

Administrations

Patients may require multiple administrations of ^{131}I. The activity prescribed is an individualised clinical decision that must be justified by a licensed practitioner.

Activity

- 1.1GBq or 3.0GBq dependent on risk factors (RRA)
- 5.5GBq (RAIT)

Administered activity should be within ±10% of the prescribed activity. All new patients should be discussed in the thyroid MDT prior to the decision to treat with radioiodine ablation. Follow-up RAIT can be discussed in the radionuclide MDT.

Pretreatment preparation

- All patients will undergo a radiation risk assessment prior to ^{131}I administration following work instruction WI-NM-121

Information for patients

- Local patient information sheet WI-NM-311

Exclude pregnancy and breastfeeding

- ^{131}I is contraindicated if the patient is pregnant, and this needs to be tested prior to administration as per EP-NM-201
- Patients must be advised not to get pregnant for at least six months after administration
- Breastfeeding should be stopped eight weeks prior to administration
- Before carrying out multiple administrations, the oncologist needs to explore the possibility of egg preservation with the patient on an individual basis

Fertility for male patients

- Male patients are advised not to try for children until at least four months after the final ^{131}I treatment
- Before carrying out multiple administrations, the oncologist needs to explore the possibility of sperm banking

Low-iodine diet

- Patients should be advised to adopt a low-iodine diet for two weeks prior to administration
- The oncologist should advise if an adjustment to booking protocol is required for patients who are routinely taking Amiodarone
- Ensure the patient has had no CT contrast within the eight weeks prior to administration

Thyroid stimulant hormone (TSH) stimulation

- See Appendix A for methods for TSH stimulation

Inpatient treatment overview (WI-NM-043)

- This could be in room 1 for paediatrics or room 2 for adults
- Pre-administration blood tests (FBC, U&E, thyroid profile, thyroglobulin, free T3, free T4 and bone profile)
- A pregnancy test should be completed on ward (if applicable)
- Comforter and carer form should be completed (if applicable)
- Anti-emetics should be given 30 minutes prior to administration
- Post-therapy uptake scan is scheduled for each patient
- External dose rate measurements should be taken by physics
- If applicable, thyroid hormone replacement (liothyronine or levothyroxine) should be restarted at the dose prescribed pretreatment unless advised differently by the oncology team

On-treatment review

- Patients reviewed weekly for radiotherapy toxicities. After completion of treatment patients are seen in outpatient clinic for regular medical review.

Follow-up appointment

- A follow-up appointment with the oncologists will be scheduled for four weeks post-treatment. MDT review of blood results and post-therapy uptake scan, with outcomes uploaded to the electronic health record system, should occur prior to outpatient visit.

Dynamic risk stratification/assessment (DRS or DRA)

The dynamic risk stratification facilitates follow-up and gives the clinical team an indication of the patient's response to treatment. Any patient who has been treated with a total thyroidectomy and RRA should undergo a DRA 9–12 months post-treatment.

As routine practice, the following investigations need to be organised:

- USS thyroid
- Stimulated blood tests
- In addition, a diagnostic ^{123}I scan may be clinically requested for patients with thyroid cancer who have known elevated thyroglobulin antibodies

Treatment letter

- On completion of treatment a summary of the treatment and toxicities experienced are documented
- In addition, expected acute and late side-effects are detailed with recommended treatments

Evidence base

- [Reference A]
- [Reference B]
- [Reference C]

Appendix 6. Example of a 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.

Online 2D verification image match competency and training record						
Name						
Task	**Date trained**	**Trainer sign**	**Date assessed**	**Assessor sign**	**Trainee sign**	**Date**
Log on *See work instruction 3.1*						
Patient record ID *See SOP 2.1*						
Filter use *See work instruction 3.1*						
Types of image match *See workbook 3.1*						
Match results *See training workbook 3.1*						
Image status *See training workbook 3.1*						
Actioning match results *See training workbook 3.1*						
Considerations for different anatomical sites *See training workbook 3.1*						
Additional training/retraining						

This record indicates that the above individual has received training, demonstrated the required understanding to the expected standards and can apply that knowledge into practice consistently and competently. The signature of the trainee indicates agreement of the above and that they have read and understood the associated procedures.

Competency demonstrated	Date	Assessor sign	Date	Trainee sign

It is the professional responsibility of the above individual to request a competency review if they feel their knowledge and skills do not meet the above criteria. The appropriate manager will remove competency from the matrix until successful reassessment has been completed.

Review requested	Date	Appropriate manager sign	Date	Trainee sign

Appendix 7a. 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 exposures

	Adrenal	Breast	CNS	GI lower	GI upper	Genitourinary	Gynaecology	Head and neck	Lung	Haemoncology	Paediatrics	Skin	Sarcoma	Stereotactic	Palliative whole brain	Palliative chest	Palliative bone 1st treatment	Palliative nodes	Palliative bone re-treatment	Emergencies
Name	**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
Name	**StR 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
Name	**Consultant radiographer**																			
	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 it 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 StRs: on return from periods of leave of >6 months, consultant should reassess a number of cases to ensure no additional training required.

Author:	Anne Smith	**Page no:**	1 of 1	**Implementation date:**	10/09/2019
Authorised by:	medical director	**Version no:**	1	**Next review due:**	08/08/2021

Appendix 7b. 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

	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
Name	**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
Name	**Medical physics staff – 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
Name	**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
Name	**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

Author:	Anne Smith	**Page no:**	1 of 1	**Implementation date:**	10/09/2019
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Appendix 8. 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, 2 weeks at the joint oncology clinic

Appendix 9. Example of local risk assessment directed at accidental and unintended exposures

Please note this is an example of how a risk assessment directed at accidental and unintended exposures 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 errors would suggest that the main areas of local risk of unintended or accidental exposure are:

a. Positional/geographical errors
b. Target volume errors (ie, incorrectly marking target volumes)
c. Imaging-related errors (eg, incorrect decision following imaging, wrong imaging factors)
d. Equipment-related errors (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 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 patients' 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/ authoritative guidance

SEVERITY				
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

LIKELIHOOD		
Likelihood score	**Chance**	**Description**
1	Rare/extremely unlikely	Very good control 0.01% chance
2	Unlikely	Good control 0.1% chance 1 in 3 years
3	Likely	Limited effective control 1% chance 1 a year
4	Somewhat likely	Weak control ≥10% chance 1 in 6 months
5	Very likely	No effective control ≥80% chance 1 in 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 errors

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 durable response rate (DRR) against patient anatomy and by imaging the patient and performing a gross error check before treatment commenced.

	Initial risk			**Following mitigation**		
Area of risk	**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 correct imaging procedure: consequence = 3, likelihood = 1, risk score = 3)

b. Target volume errors

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 artefacts left on CT slices. This is mitigated against by two subsequent planning staff checks. Could be mitigated further with peer review of target volumes, but risk score remains the same.

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

c. Imaging-related errors (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 preparation 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 preparation/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.

	Initial risk			Following mitigation		
Area of risk	**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 errors

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 radiation therapy service (RTS) 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.

	Initial risk			Following mitigation		
Area of risk	**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 the patient ID-checking process and highlighting the risk (no errors 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 is not a 100% failsafe system).
- Clinician (more likely StR) 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, fractionation or technique has been requested, unless issues of dose/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 any error (not 100% failsafe). Failure to identify the error at the prescribing point will not cause overdose (as the 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 has been made).

	Initial risk			Following mitigation		
Area of risk	**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 years) a source of error so are not specifically risk scored. Our three-point ID procedure is adhered to extremely well (likelihood = 1, consequence 4, risk score = 4).

Appendix 10. Working party membership

Helen Best	Public Health England
John Burton (Chair)	Society and College of Radiographers
David Eaton	Institute of Physics and Engineering in Medicine
Úna Findlay	Public Health England
Louise Fraser	Public Health England
Mark Gaze	The Royal College of Radiologists
Hayley James	Institute of Physics and Engineering in Medicine
Clare Leeson (Secretariat)	Society and College of Radiographers
Nazia Mohammed	The Royal College of Radiologists
Maria Murray	Society and College of Radiographers
April-Louise Smith	Institute of Physics and Engineering in Medicine

Patient Safety in Radiotherapy Steering Group Membership

Julia Abernethy	NHS England and Improvement
Helen Best	Public Health England
Martin Duxbury	Society and College of Radiographers
Úna Findlay (Chair)	Public Health England
Petra Jankowska	The Royal College of Radiologists
Tony Murphy	Lay representative
Maria Murray	The Society and College of Radiographers
Carl Rowbottom	Institute of Physics and Engineering in Medicine

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