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THE SOCIETY & COLLEGE OF RADIOGRAPHERS

Public Health England

IR(ME)R

Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine

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Foreword

Ionising radiation has been used for over 100 years in medical imaging, greatly helping patient diagnosis and treatment. Continual advances in technology have led to the increasing use of ionising radiation in many patient pathways. The benefits of using ionising radiation for diagnosis and treatment need to be weighed against the risks associated with the detrimental effects of the radiation dose. Regulations provide a framework for the safe use of ionising radiation in medical and non-medical imaging using medical radiological equipment. Guidance is required to help interpret these regulations.

The Ionising Radiation (Medical Exposures) Regulations 2017 and Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 came into force on 6 February 2018 replacing IR(ME)R 2000 and the Medicines (Administration of Radioactive Substances) Regulations 1978. 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.

This guidance seeks to explain how the requirements of the regulations should be interpreted and used in practice. It explains the principles and requirements of IR(ME)R, providing clinical scenarios to enable practical interpretation of the regulations. This document has been written in support of all staff groups involved in medical and non-medical exposures within clinical settings, both in the NHS and the independent sector, research laboratories, universities and sports facilities, where appropriate. This guidance also applies to those services using ionising radiation outside of radiology and nuclear medicine departments such as cardiology and orthopaedics. Specific guidance is available for dental exposures and therefore is not covered in this guidance.

The inclusion of diagnostic nuclear medicine into this document complements the updated radiotherapy IR(ME)R guidance, which now includes molecular radiotherapy. Every effort has been made to provide a consistent approach across the two guidance documents with shared working across the disciplines of diagnostic imaging, nuclear medicine and radiotherapy.

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

- British Institute of Radiology
- British Society of Paediatric Radiology
- Institute of Physics and Engineering in Medicine
- Medical Exposures Group, Public Health England
- Royal College of Radiologists
- Society and College of Radiographers

We would like to thank members of the working party (Appendix 8) for their time and expertise in developing this document and acknowledge the radiotherapy IR(ME)R working party for their contribution and shared working.

Particular thanks should go to Dr Peter Riley, who chaired the working party. Sadly, Peter passed away during the later stages of the development of this document. The radiology community owe him a great debt for this document. In recognition of all his valuable work as an interventional radiologist and on radiation safety the RCR has issued this document in memoriam to Dr Riley.

We hope this document will support the diagnostic and nuclear medicine communities to implement IR(ME)R in their 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) for all staff groups delivering a range of diagnostic imaging, interventional radiology and diagnostic nuclear medicine services.[1] 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.[2] Within the UK responsibility for healthcare is devolved and different approaches may be taken in each of the four nations.

Typical scenarios and examples have been included within text boxes to provide practical advice on aspects of the regulations. These are taken from information provided to the working party by several hospital trusts or health boards and are not intended to be prescriptive. A glossary of terminology used in this guidance is included in Appendix 1.

The Regulations

IR(ME)R implements the medical exposure provisions from the European Council Basic Safety Standards Directive 2013/59/Euratom (BSSD).[3] The BSSD takes into account the recommendations from the International Commission on Radiological Protection (ICRP) publication 103.[4]

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

- Reporting of accidental and unintended exposures (Chapter 21)
- Introduction of non-medical imaging exposures using medical radiological equipment which replaced and expanded upon medico-legal exposures (Chapter 18)
- Introduction of a formal recognition scheme for medical physics experts (Chapter 19)
- Introduction of licensing for employers and practitioners for the administration of radioactive substances to persons for diagnosis, treatment or research (Chapter 22)
- Existing equipment requirements moved from the Ionising Radiations Regulations 1999 and new equipment requirements from BSSD added (Chapter 20).[5]

IR(ME)R places obligations on specific duty holders and provides a framework intended to protect individuals from the hazards associated with medical and non-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 Chapter 2 (Duty holder roles and responsibilities).

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

Table 1.1: Types of exposure

	Exposure	Examples
Medical exposures	▪ Patients, as part of their medical diagnosis or treatment	▪ X-ray imaging, computed tomography (CT), fluoroscopy, interventional radiology, dual-energy X-ray absorptiometry (DXA), mammography ▪ Nuclear medicine imaging, positron emission tomography/computed tomography (PET-CT), non-imaging nuclear medicine examinations
	▪ Individuals as part of health screening programmes	▪ Imaging a group or population for a disease (eg, NHS Breast Screening Programme)
	▪ 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)
	▪ Asymptomatic individuals	▪ Investigations to exclude disease on individuals with no symptoms
Non-medical exposures	▪ Individuals undergoing non-medical imaging using medical radiological equipment	▪ Health assessment for employment, immigration or insurance purposes ▪ Radiological age assessment ▪ Identification of concealed objects within the body

This document should be read in conjunction with IR(ME)R and other published guidance.[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 within the IR(ME)R pathway. 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 or non-medical exposure to an individual
- Be able to challenge the actions and decisions, as appropriate, of others if their performance is likely to result in ineffective or unsafe delivery of 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. Doing so can avert serious adverse events.

An individual may be entitled to act as more than one duty holder (for example, referrer, practitioner and operator for an orthopaedic procedure involving fluoroscopic control). In these situations, the individual is responsible for the requirements of each of the duty holder roles they undertake [Regulation 2(2)].

Responsibility cannot be delegated. A person can delegate a task to another individual (as long as that individual is competent to undertake the task) but still retains the responsibility. This means the 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 (Training).

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 generally 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, such as referral, but they cannot be held responsible for those tasks carried out by other duty holders, such as justification.

A signature indicates the duty holder is taking responsibility for that specific task. It would be inappropriate to sign for something outside your scope of practice for which you have not been trained, are deemed competent and are entitled. Electronic signatures have been adopted in many areas of radiological practice to replace handwritten signatures.[7] Electronic signatures are only as secure as the business processes and technology used to create them. Users should be made aware of local procedures governing the use of IT and the General Data Protection Regulation (GDPR),[8] including any potential for disciplinary action if log-in details are shared.[9]

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. Examples of practical ways of demonstrating that all reasonable steps have been taken include documentation of:

- Identification checks
- Pregnancy and breastfeeding checks
- Conversations and discussion with individuals exposed
- Quality control (QC) records
- Clear, accurate and up-to-date employer's procedures.

Employer

In IR(ME)R the definition of 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 quality assurance (QA) programmes. The employer has a statutory duty to make sure these are in place [Regulation 6]. The duties of the employer are set out in Table 2.1.

Table 2.1: Requirements for 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 (Chapter 22)
Regulation 6	General procedures, protocols and QA	▪ Establish written employer's procedures required in Schedule 2 (Appendix 3) ▪ Establish written protocols for standard radiological practices ▪ Establish referral guidelines ▪ Have a QA programme in place for documentation (Chapter 3) ▪ Ensure practitioners and operators are adequately trained and engage in continuing professional development (CPD) and education after qualification (Chapter 4) ▪ Establish dose constraints for research exposures (Chapter 23) and for carers and comforters (Chapter 16)
Regulation 7	Clinical audit	▪ Ensure the employer's procedure details how and when clinical audit is carried out (Chapter 3)

Regulation	Requirement	Things to consider
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 incidents where an accidental or unintended exposure has occurred (Chapter 21)
Regulation 12(9)	Clinical evaluation	▪ Ensure that a clinical evaluation is recorded for every exposure except for carers and comforters (Chapter 11)
Regulation 13	Population doses	▪ Ensure dose estimates from medical exposures for diagnostic and interventional procedures are collected (Chapter 10)
Regulation 14(1)	Expert advice	▪ Appoint a suitable medical physics expert (MPE) (Chapter 19)
Regulations 15(1), 15(3), 15(6)	Equipment	▪ Implement and maintain an equipment QA programme ▪ Maintain an equipment inventory ▪ Implement measures to address poorly performing equipment (Chapter 20)
Regulations 17(4), 17(5)	Training records	▪ Keep appropriate training records and ensure they are available for inspection (Chapter 4) ▪ Share training records between employers (Chapter 5)
Schedule 2	Written employer's procedures	▪ A minimum requirement of 14 employer's procedures ▪ Review and update periodically (eg, 1–3 years) (Chapter 3)

Under IR(ME)R, the employer is legally responsible, when establishing practices for the safe delivery of diagnostic imaging, interventional or nuclear medicine services, 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 should describe the responsibilities of every duty holder involved in the process, including the employer.

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

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

There should be clear governance structures describing how policies, procedures and protocols are implemented. Ratification processes may be achieved through, for example, a radiation protection committee (RPC) which provides a framework for the formal adoption of documentation, DRLs, optimisation, and so on. The RPC 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.[10] In Northern Ireland, this also includes medical practitioners registered with the Medical Council of Ireland.

Referrers are entitled, by the employer, to request that an individual is exposed to ionising radiation as part of a diagnostic, interventional or nuclear medicine investigation. Referrals are made taking into account the referral guidelines provided by the employer. Many radiology departments will accept referrals from outside their organisation, for example from a general practice or a chiropractor. 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 (Training) and 6 (Referral process). Information on non-medical referrers is included in Chapter 6 (Referral process).

The roles and responsibilities of the referrer are set out in Table 2.2.

Table 2.2: Requirements for 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 (Chapter 4) (eg, process for amending or cancelling a referral)
Regulation 6(5)(a)	Referral guidelines made available	▪ Access to established guidelines that can be used to make a referral (eg, iRefer) ▪ When and how to seek advice on non-standard referrals
Regulation 8(1)	Clinically significant accidental or unintended exposures (CSAUE) are communicated to the referrer	▪ Ensure involvement in the process for CSAUE ▪ Awareness of the need for the individual exposed (or their representative) to be informed ▪ Provide advice when the decision may be not to inform the individual ▪ Understand how the outcome of analysis is shared
Regulation 10(5)	Sufficient medical data are supplied	▪ Provide enough information to identify the individual ▪ Provide information on relevant clinical history to enable justification by practitioner ▪ Where relevant provide information on pregnancy or breastfeeding
Schedule 2(b)	Individual entitlement	▪ Understand specified scope of practice ▪ Adhere to limited referral rights when they are applied

See Chapter 6 (Referral process) for further information on 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 22 (Nuclear medicine licensing).

The practitioner is entitled by the employer to justify and authorise the exposure of an individual to ionising radiation. The process of justification and authorisation is described in more detail in Chapter 7 (Justification and authorisation). To perform justification, the referral is assessed against the clinical data supplied by the referrer. The practitioner must be adequately trained and be competent to consider the potential detriment of the exposure against the potential benefits for that individual. For certain exposures, the practitioner may need to consider the benefits to society (for example, health screening or research).

Before justifying an exposure, the practitioner should review the results of any relevant previous imaging and consider the suitability of alternative imaging techniques that do not involve the use of ionising radiation. The roles and responsibilities of the practitioner are set out in Table 2.3.

Table 2.3: Requirements for the practitioner

Regulation	Requirement	Things to conside
Regulation 10(1)	Employer's procedures	▪ Read and comply with employer's procedures
Regulation 5(1)(b)	Licence for administered activity	▪ Hold a valid practitioner licence (Chapter 22) ▪ Understand what is specified in the licence ▪ Adhere to the terms of the licence
Regulation 10(2)	Justification of the exposure	▪ Weigh up benefit and risk ▪ Request further information if required ▪ Authorise referrals that are justified
Regulation 10(6)	Co-operate with other staff	▪ Share relevant information ▪ Participate in multidisciplinary team meetings ▪ Get medical physics support and advice ▪ Work together with other specialists and duty holders
Regulations 11(2), 11(3), 11(4)	Justification of exposure	▪ Evaluate the information provided ▪ Consider the data supplied to establish net benefit ▪ Consider the urgency of the exposure

Regulation	Requirement	Things to conside
		▪ Consider justification of exposures to carers and comforters and asymptomatic individuals ▪ Take into account guidelines issued by professional or relevant bodies ▪ Choose a modality that best addresses the clinical problem ▪ Authorise referrals that are justified
Regulation 11(5)	Task of authorisation	▪ Issue authorisation guidelines to be used by operators ▪ Retain responsibility of justification for referrals authorised under guidelines
Regulation 12(1)	Optimisation	▪ Ensure exposures are kept as low as reasonably practicable ▪ Use non-ionising radiation modalities where appropriate ▪ Be aware of and use local and national DRLs
Regulation 12(8)	Pay particular attention	▪ Optimisation of: ▪ Paediatric exposures (Chapter 15) ▪ Health screening programme exposures (Chapter 17) ▪ High-dose exposures (Chapter 10) ▪ Pregnancy status (Chapter 13) ▪ Breastfeeding status (Chapter 13)
Regulation 17(1)	Training	▪ Adequate training as defined in Schedule 3 (Chapter 4) ▪ Training on and competency in local equipment and techniques ▪ Training on new techniques and technology
Schedule 2(b)	Individual entitlement	▪ Understand specified scope of practice (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. The scope of practice may be limited; for example, to justification of general radiography, CT, interventional procedures, nuclear medicine, and so on. It is important to define this in the employer's procedures.

Operator

There is no requirement for the operator 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 of an exposure [Regulations 10(3) and 17(1)]. The operator is individually responsible for all practical aspects of a procedure they undertake.

Some examples of practical aspects include:

- Patient identification
- Checking pregnancy or breastfeeding status
- Operating the imaging equipment
- Optimisation
- Initiating the exposure
- Contrast administration
- Dispensing/administration of a radiopharmaceutical
- Image manipulation and archive
- Clinical evaluation
- Quality control checks.

Operator functions may also be carried out by the MPE or other trained medical physics staff including medical physicists 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 operators. In most circumstances, third-party engineers, whether providing initial installation or servicing, are responsible for presenting equipment 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. The roles and responsibilities of the operator are set out in Table 2.4.

Table 2.4: Requirements for 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 ▪ Allocation of responsibility to appropriate specialist staff
Regulation 10(6)	Co-operate with other staff	▪ Share relevant information ▪ Liaise with other duty holders involved in an individual exposure ▪ Participate in multidisciplinary team meetings ▪ Get medical physics support and advice
Regulation 12(1)	Optimisation	▪ Ensure exposures are kept as low as reasonably practicable ▪ Be aware of and use local and national DRLs
Regulation 12(3)	Selection of equipment and methods	▪ Choose the most appropriate equipment and method for the individual being exposed ▪ Ensure exposures are as low as reasonably practicable (ALARP) by using techniques such as screen grabs, low pulse rate, prospective gating ▪ Assess and evaluate dose during and after the procedure
Regulation 12(8)	Pay particular attention	▪ Paediatric exposures (Chapter 15) ▪ Health screening programme exposures (Chapter 17) ▪ High-dose exposures (eg, some CT and interventional) (Chapter 10) ▪ Pregnancy status (Chapter 13) ▪ Breastfeeding status (Chapter 13)

Regulation	Requirement	Things to consider
Regulation 17(1)	Training	▪ Adequate training to carry out any practical aspect of an exposure (Chapter 4) ▪ Training on and competency in local equipment and techniques
Schedule 2(b)	Individual entitlement	▪ Understand specified scope of practice (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. Individual training records for operators require regular review as individuals develop and equipment and techniques change.

A medical exposure using ionising radiation must only be performed by an operator who has been trained, is deemed competent and is entitled to perform these procedures by the employer. The operator is responsible for checking patient demographics, as provided, to ensure the correct individual is being examined, and for ensuring the appropriate imaging protocol is used. Further information on training requirements is available in Chapter 4 (Training).

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 clinical technologists and radiographic assistant practitioners (APs). It is important to note that the term 'practitioner' in this context is different from the term as defined by IR(ME)R.

Although not a requirement of IR(ME)R, radiographic assistant practitioners may be accredited by the College of Radiographers (CoR) and entered onto the CoR public voluntary register.[11] 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 supervision, 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 the Institute of Physics and Engineering in Medicine (IPEM).

They are eligible to join an assured Register of Healthcare Science Practitioners through the AHCS or the assured Register of Clinical Technologists through IPEM. The assured registers are accredited by the Professional Standards Authority.

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 for all staff groups. When these individuals are acting as entitled IR(ME)R operators, they are legally responsible for their actions.

3. Employer's 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 practice 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)]. These protocols should be locally established, in collaboration with the MPE, taking into account service delivery and available equipment. Where possible, a local standard template should be considered for these 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 20 (Equipment and quality assurance).

Regulation 2 of IR(ME)R defines QA as 'any planned and systematic action necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with generally applicable standards and QC is part of quality assurance'.

The benefits of using a robust QA programme include:

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

The employer is responsible for implementing IR(ME)R requirements across the range of services using ionising radiation within the organisation. An organisation-wide document may be established to achieve this (for example, within a radiation safety policy). Care needs to be taken to ensure local, modality-specific procedures are consistent with any organisation-wide documents. For example, where entitlement of practitioners differs between radiology and nuclear medicine, this should be clearly stated.

A key component of a QA programme is the control and management of documentation. Table 3.1 includes matters to consider when establishing a QA programme for documentation.

Table 3.1: Considerations when establishing a QA programme for documentation

QA programme	Things to consider
How are written procedures and protocols developed and established?	Process should include: ▪ Standard template, consistent terminology and page numbering ▪ Engage appropriate subject experts ▪ Clear governance arrangements ▪ Clarify who is responsible for review process and accuracy of content ▪ Clearly identify the authors ▪ Define document authorisation process ▪ Potential use of quality management software ▪ Training for staff
How is assurance of service quality provided to the employer?	▪ Audit of compliance ▪ Regular feedback to governance teams
How are procedures and protocols reviewed?	Process should: ▪ Include clear governance arrangements ▪ Describe the review process to incorporate staff feedback ▪ State who is responsible for document review ▪ Describe version control ▪ Document revision history, summary of changes, signature, date of approval and next review date ▪ Include outcomes of internal audit, nonconformities or observations from external audit, inspection or incident investigations
How frequently should reviews occur?	▪ Local decision: commonly completed every two to three years or following change in service delivery, legislation or similar, based on whichever is the minimum

QA programme	Things to consider
How and where can staff access procedures and protocols?	▪ Read-only electronic documents (intranet/shared network drive/quality management system) ▪ Paper documents (avoid multiple uncontrolled copies or versions, and to allow access in the event of a network failure) ▪ 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) ▪ Newsletters, memos, etc ▪ Electronic quality management systems (QMS) software ▪ Communication with others outside the department (eg, referrers, cardiologists)

The management of written procedures should ensure that only the current version of any document is available and used by staff. Where hard copies of procedures or protocols are made available, a disclaimer should be included to say 'uncontrolled when printed'. Old hard copies must be removed from circulation.

Written protocols include descriptions of how an examination is carried out. They should be evidence-based, reflect current practice and be ratified through the QA process.

Examination protocols, embedded in the radiological equipment, require additional management to ensure they are locked and changes cannot be made by unauthorised staff. Software updates may change agreed examination protocol settings, therefore copies of protocols should be backed up. A system should be in place to communicate system changes. Further detail on handover processes is included in Chapter 20 (Equipment and quality assurance).

A robust management system is essential to ensure consistency between written protocols and examination protocols embedded within the equipment. Where possible, embedded protocols should be locked. Backup copies must be kept and maintained so that staff can check the embedded protocols are correct.

External review and accreditation schemes for imaging services including QA programmes are available, such as the Quality Standard for Imaging,[12] but there is no requirement for this in IR(ME)R.

IR(ME)R audit

The QA programme should cover all aspects of the diagnostic imaging process, including practices involving non-medical imaging and non-imaging nuclear medicine examinations. To ensure the QA programme is being followed and written procedures are complied with, a system of regular IR(ME)R audit is essential. A schedule of IR(ME)R audit may be drawn up on a rolling programme to check employer's procedures are in place and being followed.

Some examples of IR(ME)R audits are included in Table 3.2, 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 confirm their entitlement? ▪ How and where is this recorded? Are operators complying with the procedure?
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 (eg, GPs)?
Operator training records	▪ Are records available and up to date for all operators? ▪ Do competency records reflect available equipment and processes?

Audit	Things to consider
DRLs	▪ Have DRLs been reviewed as per the employer's procedure? ▪ Are doses or administered activities accurately recorded? ▪ What action is taken where DRLs are consistently exceeded?
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 of the exposure in a sample of patient records?
Image quality and technique	▪ Is there a process for reviewing reject analysis?

Clinical audit

Regulation 7 requires the employer to have in place a programme for clinical audit. Audit is a tool for reviewing and improving healthcare outcomes and ensuring patient care is provided in line with best practice standards.[13] Change should be implemented where practice is deemed to fall short of the standard and, after a specified 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.[14]

Audit will help identify:

- How well a department is performing against pre-defined 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 changes in practice are needed
- Where new standards or benchmarks are required.

Clinical audit should be an established part of every radiology and nuclear medicine department 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.[15] It should aim to enhance the provision and organisation of clinical services through the promotion of effective use of resources and identify the changes needed to improve the standard of practice.

A multidisciplinary team approach to establishing and carrying out an audit programme will yield the most effective results. An example of this would be an image optimisation team (IOT)who may jointly manage dose audits, optimisation and review of protocols.[16]

With increasingly complex equipment and techniques, maintaining quality in radiology and nuclear medicine should be responsive and wide-ranging. It must be measured and re-evaluated against best practice standards using peer-reviewed publications and from the wider community, not solely through internal departmental audit.

Clinical audits 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 change should happen. Results of clinical audit should be made available to the employer.

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, 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 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 training and reflect an individual's continuous development and local department-specific training, as well as that achieved through pre- and post-registration qualifications. An example of a local training record is included in Appendix 4.

Before operators use a new piece of equipment unsupervised, they must complete a training programme and a record should be made of this training. This includes the use of equipment at different sites, even though the same make and model may be installed across many departments. While some equipment may appear familiar, there may be differences in how, for example, the protocols on CT scanners have been constructed and how these differences could affect both dose and image quality.

Training is also required in the communication of the benefits and risks from exposures with patients or other individuals exposed, such as carers and comforters.

Training records of all staff entitled to act as practitioners and/or operators should be reviewed and updated on a regular basis, perhaps as part of the appraisal process, 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 and registration 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 they do for permanent employees.

Adequate training

Schedule 3 of IR(ME)R outlines the areas of theory and practice necessary for the training of practitioners and operators 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, refers to 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 may be scope for further development in many of these areas and a need for further training in others. For example, when upgrading an imaging room from computed radiography (CR) to digital radiography (DR) all relevant staff will need to be trained in the use of the new equipment. Practitioners and operators should consider the need for further training prior to any extension to their scope of practice, especially when that crosses the boundary between diagnostic radiography, radiotherapy and nuclear medicine; for example, PET-CT or MR radiotherapy [Regulation 6(3)(b)]. A training framework is particularly relevant where hybrid imaging techniques are introduced.

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 for individuals who are anxious, vulnerable or have communication challenges. Operators and practitioners should demonstrate compassion and, where appropriate, act as the individual's advocate.[17,18]

MPEs must be appropriately entitled as IR(ME)R operators for specific tasks and keep an up-to-date record of their knowledge and training. An individual can only be entitled as an MPE if they are recognised by the Secretary of State in Great Britain or the Department of Health in Northern Ireland. The Department of Health and Social Care has established a UK-wide MPE recognition scheme and has appointed RPA2000 as the assessing body.[19,20] The employer must appoint a suitable MPE and ensure they are involved to the extent required by Regulation 14 (Expert advice). MPEs will acquire a different set of knowledge and skills relating to the operation of imaging equipment. More information on this can be found in Chapter 19 (The role of the medical physics expert). The MPE's unique skill set must be utilised during the equipment procurement process and may involve, for example, discussions with existing users or manufacturers' product specialists.

MPEs are required to develop a large portfolio of skills to enable them to have a clear understanding of the capabilities and relational factors of the equipment they look after. The MPE should continue to develop their knowledge and understanding of equipment performance, for example by working with engineers and applications specialists during planned upgrades or installations.

MPEs may be expected to work across a wide range of sites using many different makes and models of imaging equipment. At the point at which they become an entitled operator under IR(ME)R, the employer must be assured that the MPE is adequately trained to operate and work on the equipment. Where MPEs are contracted by a different employer under a service-level agreement, training records should be made available.

Clinical technologists may similarly acquire ongoing knowledge and skills across a wide range of equipment relevant to their area of expertise. They must keep an up-to-date record of their training, which may include graded competencies related to the technical level at which they are authorised to operate the equipment. At the point at which they become an entitled operator under IR(ME)R, the employer must be satisfied that the clinical technologist has evidenced adequate training for each piece of equipment.

MPEs and clinical technologists should be considered for inclusion with other operators (eg, radiographers, radiologists and cardiologists) in the training provided by manufacturers' applications specialists when new equipment is installed.

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.

Practitioner training records

Professional qualifications in clinical radiology or nuclear medicine, for example Fellowship of the RCR (FRCR) by examination and the subsequent award of a Certificate of Completion of Specialist Training (CCT) by the General Medical Council (GMC), provide suitable evidence of competence to act as a practitioner. Practitioners in nuclear medicine 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)]. This is issued on the basis of specialist training and experience. This may be further guided by recognition of subspecialisation, and entitlement should be appropriate to the skills and level of training and experience of the individual.[21]

Employer's procedures should specify training requirements for IR(ME)R practitioners who are not medically qualified, such as radiographers. The training records should demonstrate appropriate skills, knowledge, experience and assessed competence within a clearly defined scope of practice. The Society and College of Radiographers has provided guidance on what should be included in IR(ME)R practitioner training.[22]

A radiographer is trained and entitled to justify and report musculoskeletal general radiography images of the upper and lower extremities. Their additional training is recorded. To justify these exposures, they are entitled as a practitioner, within a defined scope of practice. To report these exposures, they are entitled as an operator, within a separate, defined scope of practice. Both training and entitlement records will reflect their additional learning and its application to the clinical setting.

Operator training records

Training records for operators should be detailed and up to date, reflecting training and competency achieved for learned skills. All healthcare staff professionals (including doctors, assistant practitioners and MPEs) acting as operators must have regularly updated training records that reflect their scope of practice for each piece of equipment and for similar equipment across different sites.

Staff who have not had specific training on working with ionising radiation as part of their professional qualification (for example, orthopaedic surgeons) may undertake operator roles after appropriate theoretical and practical training.

Trainees (for example, 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.

A department has a new fluoroscopy room installed. Following satisfactory completion of medical physics acceptance testing, a core team of radiographers and radiologists who will use the equipment are scheduled to have training on using the new unit by the manufacturer's application specialist. One of the MPEs responsible for the equipment QC and optimisation is invited to attend the training.

The core team then cascade the training using theoretical and practical sessions to others in the department, and a competency checklist and training record are developed by the service lead. The checklist and record are completed by every operator prior to working unsupervised and being entitled by the employer. Training records for this equipment are reviewed, in line with the standards described in the employer's procedures and following software updates.

A radiology registrar transfers to a new hospital as part of a rotational educational programme and is scheduled to perform a barium screening list. As part of an earlier placement at a different hospital, the registrar received equipment training on a similar fluoroscopy unit and was entitled as an operator at that site for screening lists. The registrar has an up-to-date training record reflecting this training. Before the first screening list a training session is completed with the lead radiographer in the fluoroscopy suite. The lead radiographer highlights the specific set-up of the fluoroscopy units and identifies the differences between the similar pieces of equipment and protocols. The lead radiographer supervises the registrar throughout their first fluoroscopy session and then completes and updates the registrar's training record. They are entitled as an operator by the employer at this site.

Supervision including students and trainees

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

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

An operator who supervises a trainee may provide evidence that the trainee has successfully completed training, including theoretical knowledge and practical experience, to be deemed adequately trained and competent 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 (Entitlement).

A trainee (for example, a student radiographer or trainee assistant practitioner) is unlikely to meet the requirements of Schedule 3, adequate training, to be entitled as an operator until they have completed a full programme of assessment. Until this time, Regulation 17(3) applies, which permits 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 professional bodies on what constitutes adequate supervision of trainees.[23–27] 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.

Where a person carrying out a task is considered fully trained and competent to do so, it is normally appropriate that they should be entitled to act as an operator in their own right.

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 radiologists, who will already be medically qualified but who may not necessarily be trained in radiation protection, the scope of their entitlement, as both practitioner and operator, should be commensurate with their 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:

- 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 the GDPR, including any potential for disciplinary action if log-in details are shared
- How to access referral guidelines, including information on radiation dose
- The specific examinations included in a non-medical referrer's entitled scope of practice
- Professional and legal responsibilities.

Referrer training may reduce the number of errors (inappropriate or repeat examinations) caused by incorrect patient identification at the time of the referral. The Society and College of Radiographers (SCoR) has published an IR(ME)R referrers' checklist for referring a patient for a diagnostic imaging examination.[28]

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

Joint professional body guidance is available for referrers who are not medically qualified, such as nurse practitioners, physiotherapists and chiropractors and further information is given in Chapter 6 (Referral process).[29,30]

Employers should ensure that all referrals for examinations involving the use of ionising radiation are appropriate through regular audit. This should be part of an overarching radiation protection governance and assurance programme which promotes education and service improvement.

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 of the procedure to:

- Alert the referrer that additional information is required
- Alert the referrer that an exposure has not been justified
- Alert the referrer that the department has been unable to contact the individual for whom the exposure is intended
- Ensure referrals are appropriately prioritised and expedited as required
- Manage future appointments at specific time intervals (for example, follow-up scans)
- Address patient queries regarding their examination.

Paper systems and radiology information systems (RIS) should be fit for purpose, and users should receive training as appropriate to their role in the referral to diagnosis pathway. Referral processes are discussed in Chapter 6 (Referral process).

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 authorise, on behalf of the employer, that a duty holder or a group of duty holders have been adequately trained and deemed competent in their specific IR(ME)R duty holder roles.

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 (Training).

There is a requirement to have an employer's procedure to identify individuals entitled to act as IR(ME)R duty holders [Schedule 2(b)]. 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 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 ▪ Those using ionising radiation outside the imaging 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	▪ Relevant qualifications (eg, FRCR Part 1 for radiologists, BSc (Hons) or equivalent for radiographers, MSc for clinical scientists)
Confirmation of registration for referrers and practitioners	▪ Process for checking individuals are registered healthcare professionals as defined in the National Health Service Reform and Healthcare Professions Act 2002[10]
Confirmation of practitioner licence for administration of radioactive substances	▪ Records of valid licences, and process for renewal before expiry

Entitlement procedure	Things to consider
How individuals/groups demonstrate their entitlement and scope of practice	▪ Entitlement letter or documents 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, are 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 should be trained, assessed competent 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 procedure must also incorporate those duty holders and areas outside the imaging department where ionising radiation is in use, such as cardiology, orthopaedics or rheumatology services. 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 nuclear medicine or PET-CT examinations, the employer should ensure that the individual's licence is valid. Further information on licensing is included in Chapter 22 (Nuclear medicine licensing).

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 (See example scope of practice, Appendix 5).

Scope of practice

A scope of practice describes a range of skills and tasks based on professional registration, education, training, knowledge and experience. A scope of practice 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 permitted to undertake. This scope of practice should be updated when, for example, there is a new service requirement, 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, a nurse working in a clinic may be entitled to refer specific groups of patients for pre-treatment chest X-rays, or orthopaedic consultants may be entitled as IR(ME)R operators to clinically evaluate extremity images.

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.

The CT clinical lead radiologist in a radiology department is keen to develop staff and improve efficiency within the department. The radiologist spends time training and supervising the CT clinical lead radiographer in the justification of a range of CT examination referrals. Once the radiographer is deemed competent by the supervising radiologist, the entitlement records are updated with the radiographer's new scope of practice. The competency documentation relating to this training is signed off by the supervising radiologist and is added to the radiographer's training records. Once this has been completed the CT radiographer may then be entitled, by the employer, to act as a practitioner justifying and authorising these specific CT examinations.

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 trained to perform general radiography for a defined scope of practice **Entitle as an operator**	▪ Training programme and records ▪ Audit of practice

Professional roles and duty holders	Things to consider
Medical physics expert/medical physicist/ clinical technologist **Entitle as an operator**	▪ Where MPE advice is provided under contract, the MPE must be entitled by each employer
Orthopaedic surgeon/podiatrist using mini C-arm without a radiographer present **Entitle as a referrer, practitioner and operator**	▪ Training programme including specific IR(ME)R/radiation protection and equipment training ▪ Up-to-date records ▪ Appropriate registration for referrer and practitioner entitlement ▪ Audit of practice
Group entitlement, such as nurse practitioners in emergency departments who refer and clinically evaluate images within a defined scope of practice **Entitle as a referrer and operator**	▪ Training programme including specific IR(ME)R/radiation protection training ▪ Up-to-date records ▪ Appropriate registration for referrer entitlement ▪ Audit of practice
Third-party provider undertaking justification and clinical evaluation **Entitle as a practitioner and operator**	▪ Qualifications, registration and appropriate training checked, and records available (maintained by third-party employer) ▪ Appropriate registration for practitioner entitlement ▪ Training records should be made available by third-party provider to the employer on request ▪ Audit of practice
Agency radiographer **Entitle as an operator, referrer and/or practitioner depending on professional background, within a defined scope of practice**	▪ Qualifications, training and registration checked ▪ Induction programme including records for locally delivered training (eg, equipment) ▪ Agency should provide training records on request

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 practitioners in the employer's procedures if they are carrying out the justification process and as operators if they are performing clinical evaluation or other practical aspects. This 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 examinations 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, but 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.

Two NHS trusts work together to provide specialist podiatry services, including use of a mini C-arm in theatre. The consultant podiatrist is employed by Trust A and is entitled as referrer, practitioner and operator. The consultant podiatrist also provides similar services at Trust B, using their mini C-arm, to reduce distance and travel time for the patients. The consultant podiatrist is entitled by Trust B as a referrer, practitioner and operator, is following the employer's procedure at Trust B when working there and has had a formal induction including training on processes and equipment.

Two NHS trusts work together as a consortium to provide PET-CT services. Trust A holds an employer licence and employs three licensed practitioners. Trust B holds an employer licence and employs six licensed practitioners. To meet waiting time targets, patients may be booked into available scan slots at either Trust A or B. Where patients transfer from one trust to another, the entitlement of duty holders and the process for justification and authorisation of referrals is clear.

Trust A entitles practitioners and operators at Trust A only. Trust B entitles practitioners and operators at Trust B only.

A referral is received at Trust B and justified and authorised by one of the six licensed practitioners. There are no available scanning slots at Trust B within the waiting time target, so the referral is transferred to Trust A.

At Trust A, one of the three licensed practitioners has issued authorisation guidelines to allow operators at Trust A to authorise referrals. The authorisation guidelines include criteria that any PET-CT referrals that have been justified by any of the six licensed practitioners at Trust B may be authorised. The licensed practitioner at Trust A who issued the authorisation guidelines is the IR(ME)R practitioner for these referrals. Reciprocal authorisation guidelines are in place at Trust B.

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.

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.

Duty holders have responsibilities under IR(ME)R at each step of a patient pathway. 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 radiation doses, and make these available to referrers **Regulation 6(5)(a)**	▪ Use *iRefer* as a basis for the development of referral guidelines[31] ▪ Include radiation dose information ▪ Process to ensure all referrers have access to referral guidelines (including new referrers) ▪ Process to ensure referrers understand their responsibilities under IR(ME)R within their individual scope of practice ▪ Audit quality of referrals (including shared learning)
Referrer must supply sufficient medical data for practitioner to enable justification **Regulation 10(5)**	Include on a referral: Essential information: ▪ Accurate, up-to-date patient identification information ▪ Relevant clinical history ▪ Clinical diagnosis ▪ Requested examination ▪ Information related to research trials (where relevant) ▪ Information related to pregnancy and breastfeeding (where relevant) ▪ Signature of referrer ▪ Referrer name and contact details Expected information: ▪ Clinical findings on examination ▪ Mobility status (eg, requires hoist) ▪ Co-morbidities (where relevant) ▪ Medication (where relevant) Desirable information: ▪ Carer or comforter requirements or other relevant radiation protection information

Regulation	Things to consider
Practitioner must consider information supplied by referrer to justify each individual exposure and avoid unnecessary exposures **Regulation 11(4)**	▪ Process for contacting referrer ▪ Documentation of discussions with referrer ▪ Process for returning referrals

The referrer must supply sufficient medical data (for example, previous diagnostic information or medical records) for the practitioner to be able to weigh up the benefit of the exposure against the risks [Regulation 10(5)]. Further information on the justification process is included in Chapter 7 (Justification and authorisation).

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

Referral guidelines

The employer has responsibility for putting referral guidelines in place and making sure these are available to referrers [Regulation 6(5)(a)]. Referral guidelines set out the conditions in which an individual would typically be referred for a specific type of exposure and must include an estimate or indication of the radiation dose associated with that exposure.

In diagnostic imaging and interventional radiology, iRefer is often used as the basis for developing or updating an organisation's referral guidelines. Healthcare professionals outside the radiology department may use documented pathways in a particular specialty, which may include the most appropriate imaging tests. Where local specific examinations are undertaken, not included in iRefer, referral guidelines need to be written.

In nuclear medicine and PET-CT, BNMS guidelines, EANM guidelines and the PET-CT evidence-based guidelines are often used.[32–34]

MDT referrals should include the name of the individual making the referral.

Referrer training

While not explicitly required under IR(ME)R, it is considered best practice that, where practicable, referrers complete some form of local awareness training. A resource to encourage referrers to pause and check prior to making a referral was introduced in 2017.[28]

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 these staff to ensure referrals are actioned in a timely and consistent manner. More details on referrer and administrative staff training can be found in Chapter 4 (Training).

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.[9] The employer's procedure should address potential safety risks when using paper referral forms; for example, prohibiting the use of blank pre-signed paper 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. Audit is an effective tool to evaluate the quality and accuracy of referrals and can help to identify referrer training needs. Published audit tools are available for referrals.[35]

The CQC has reported that the most commonly notified error was the 'wrong patient' being referred for imaging.[36] As part of a constructive safety culture, the referrer should be notified and given the opportunity to contribute to any error, near miss or investigation involving an incorrect or inaccurate referral they are involved in.

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.

There are a number of different processes involved with referrals for an examination involving ionising radiation. These must be clearly described in written procedures and employers should consider providing training for everyone involved in the referral process.

Non-medical referrers

There are several groups of non-medical-registered healthcare professional referrers (NMRs) who, as part of their extended role, may request to be considered to refer. The process may start with a formal request that describes the reason, scope of practice and service delivery improvement this individual will provide for the organisation. The process may also describe the training programme, competency sign-off and self-audit processes to be completed before entitlement would be granted. The criteria for entitlement will be agreed locally by the service accepting referrals and entitling the NMRs. A clinician who is an entitled referrer should take responsibility for providing mentorship, guidance and governance to individual NMRs or teams of NMRs.

The entitlement of NMRs is the responsibility of the IR(ME)R employer; however, the task of entitlement is often delegated to an appropriate individual within the organisation, such as the clinical director for radiology. It is anticipated those tasked with entitling NMRs will have set the standards and evidence of training required, and that until the NMR provides all documentation, entitlement will not be granted. If it is reported, or audit demonstrates, that an NMR is repeatedly acting outside of their agreed scope of practice the decision may be made to remove their entitlement.

A list of entitled NMRs must be available to all practitioners and operators, along with their scope of practice. This list should be reviewed on a regular basis, enabling new NMRs to commence practice while removing those who are no longer entitled to refer.

All the referrer duty holder requirements of IR(ME)R apply to NMRs. At present, physicians' associates cannot be entitled as referrers under IR(ME)R as they are not registered healthcare professionals. However, this may change in the future and this may also apply to other staff groups.[37]

NMRs may be:[29]

- Referring as part of a clinical team where they will act on a radiology report rather than clinically evaluate the images themselves. An example is an orthopaedic specialist physiotherapist.
- Referring as part of a clinical team where a clinician will undertake the clinical evaluation. An example is a radiographer referring for SPECT-CT imaging following completion of a planar bone scan.
- Referring as an autonomous healthcare professional, clinically evaluating the images and treating the patient prior to a radiology report being issued. An example is an advanced nurse practitioner in a minor injuries unit.

While training for referrers is not a requirement of IR(ME)R it is expected that all NMRs will have had appropriate training in order for them to be entitled. Training may be delivered via an educational institution, in-house or eLearning, or by a combination of all approaches. Medical specialists in the appropriate clinical area may provide relevant clinical in-house training, while radiology staff and MPEs may also be involved with the training of NMRs.

Table 6.2: Examples of theoretical and practical training for NMRs

Training	Examples of training to be undertaken
Theoretical	▪ Principles of radiation protection ▪ Legal and professional responsibilities ▪ Responsibilities in relation to patient safety and clinical governance ▪ Benefits and risks of examinations within their scope of practice ▪ Referral guidelines for scope of practice
Practical	▪ Face-to-face learning, including time spent in relevant imaging modalities ▪ Local referral pathways ▪ Training on electronic referral systems including cancellation process ▪ Employer's procedures that must be read and followed

It is considered good practice when employers include NMRs in their audit programme. Newly entitled NMRs may be audited at more regular intervals initially, enabling departments to be assured of their compliance with IR(ME)R and that the NMR is acting within their agreed scope of practice.

NMRs should complete update training on a regular basis (for example, at least every three years).

7. Justification and authorisation

Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose. The benefit may not only be to the individual exposed but to society as a whole. An example of this may be emigration/immigration chest X-rays, which may also safeguard the community the individual joins.

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:

- Patients as part of their own medical diagnosis or treatment
- Individuals as part of health screening programmes
- Patients or persons voluntarily involved in research programmes
- Carers and comforters
- Asymptomatic individuals
- Individuals undergoing non-medical imaging using medical radiological equipment.

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.

When justifying an exposure, there are a number of considerations for practitioners to take into account. Some examples are:

- Will the exposure contribute to, or change, the individual's healthcare management?
- Has the referrer provided enough relevant clinical information to be able to justify the exposure?
- Has the referrer provided enough information to be able to definitively identify the patient?
- Is the exposure likely to answer the clinical question being asked?
- What relevant previous imaging is available?
- Are there alternative techniques that will answer the question but do not involve ionising radiation?

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

Regulation 11(4) requires the practitioner to take note of all the data provided by the referrer 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 of the examination should also be taken into account [Regulation 11(3)(d)(i)]. For example, if pregnancy cannot be excluded, especially if the abdominal and pelvic areas are to be exposed, or where the exposure involves the administration of radiopharmaceuticals, then the practitioner must consider both the individual concerned and their unborn child. The practitioner should consider whether the exposure could be delayed until it is confirmed whether the individual is pregnant or indeed consider if the exposure can wait until the baby is born. The clinical risk of delaying the exposure should be weighed up against the risk of the exposure.

When justifying an exposure to an individual who is breastfeeding, the urgency of a nuclear medicine examination should also be taken into account [Regulation 11(3)(d)(ii)]. Consideration should be given, where appropriate, to delaying the test 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 (Pregnancy and breastfeeding enquiries).

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

IR(ME)R Regulation 11(2)		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? ▪ Previous imaging, medical history, age, pregnancy or breastfeeding status, body habitus ▪ For nuclear medicine 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 investigation
(b)	**The total potential diagnostic or therapeutic benefits to the individual and society from the exposure**	▪ What is the expected benefit of the exposure? ▪ Is the exposure likely to answer the clinical question? ▪ Will the individual's treatment be altered?
(c)	**The detriment the exposure may cause**	▪ What is the likely dose from the exposure? ▪ What is the risk to the individual from that dose? ▪ Nuclear medicine patients with caring responsibilities, those who are hospital inpatients and those who may have close contact with other people after the investigation may require additional radiation protection advice ▪ Potential exposure to carers and comforters

IR(ME)R Regulation 11(2)		Consider
(d)	**What other alternative imaging modalities are available that could answer the diagnostic question but involve less or no radiation?**	▪ How effective are any alternative techniques compared with the planned exposure? ▪ Is the alternative available locally in a clinically acceptable timeframe?

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)]. When the justification process is carried out the practitioner must demonstrate this has been completed by authorising the exposure. Authorisation may be demonstrated by, for example, signing or initialling the referral in a predetermined place or by entering an electronic password. The employer's procedures should describe clearly how authorisation is to be demonstrated.

A third-party provider radiologist is telephoned to discuss an urgent referral for an out-of-hours CT scan. As the radiologist has no access to the RIS, they cannot authorise the scan, so they follow the employer's procedure and contact the on-call CT radiographer. The CT radiographer checks the radiologist is included on the list of the third-party radiologists entitled as practitioners by the employer. The radiologist justifies the scan, confirms the protocol to be used and verbally authorises it. The radiographer completes the RIS record and, in doing so, verifies the verbal authorisation and includes the details of the radiologist as the justifying practitioner.

Where the practitioner justifying an examination does have access to the RIS, it is expected they will carry out the process of authorisation following on directly from the justification process.

It is not always possible for a practitioner (for example, a radiologist) to review every imaging referral, so the regulations allow for an appropriately entitled operator to authorise an exposure following written authorisation guidelines issued by a practitioner.

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, or the patient's condition, fall outside the criteria listed in the authorisation guidelines, the operator cannot authorise the exposure and justification and authorisation by a practitioner are required.

In many departments and clinics, radiographers and other healthcare professionals (for example, orthopaedic surgeons and speech and language therapists) are entitled as practitioners for a specific range of diagnostic procedures. These individuals must be registered healthcare professionals, appropriately trained, deemed competent and entitled as a practitioner as specified in the employer's procedures.

Authorisation guidelines

Authorisation guidelines must be issued by one named practitioner (often, but not always, the lead radiologist for that area or lead licensed practitioner for nuclear medicine). 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. Published criteria such as the *iRefer* or PET-CT guidelines may be used to form the basis of local authorisation guidelines.[32,34] The authorisation guidelines should reflect current best practice and take into account local service provision. Authorisation guidelines should be clearly written using precise statements that are unambiguous in order to allow the operator to confirm whether the referral can be authorised.

While referral guidelines such as those produced by the RCR (for example, iRefer) are not sufficiently detailed for use as local authorisation guidelines, they could be considered to be a suitable starting point for their development.

In a hospital that has a number of subspecialty areas such as paediatric radiology, neuroradiology or cardiology, there may be a set of authorisation guidelines for individual areas, each produced by a different practitioner. In some imaging departments, authorisation guidelines may be used in one area (for example, CT) but not in others (such as general radiography or nuclear medicine). However, where they are issued, the operator responsible for authorising, following the guidelines, must be clearly identified and appropriately entitled as specified in the employer's procedures. It must be possible to identify who the practitioner is for each exposure performed and who has authorised the exposure.

In general radiography, a referral is received by a radiographer, who reviews the clinical information provided by the referrer in the context of the clinical question the referrer is asking. The radiographer, acting as the practitioner, considers the benefit of the exposure as well as any potential risk associated with the use of ionising radiation. They consider the age of the individual, any relevant previous imaging and associated clinical evaluation, and other imaging modalities using less or no radiation, and they review pregnancy status, where appropriate. If the radiographer considers the procedure to be justified, they authorise the exposure, which can then be carried out.

The radiographer in this scenario must be appropriately entitled by the employer as a practitioner, and will need to be trained, deemed competent and act within their defined scope of practice.[22] Training and competency records must be completed before being entitled by the employer as a practitioner. It is the employer's responsibility to keep up-to-date training records; however, this task is often delegated to others, such as a radiology services manager. This should be clearly described in the employer's procedures.

A CT scanning unit receives a referral, which is reviewed by a radiographer, who assesses the clinical information provided by the referrer. The radiographer will consider this information against a set of authorisation guidelines produced by the lead consultant radiologist. If the information is covered by the authorisation guidelines, the radiographer documents that the examination is authorised, and the medical exposure can then be carried out.

In this scenario, the lead consultant radiologist is the practitioner justifying the exposure. The radiographer is acting as an operator authorising the exposure following the authorisation guidelines. The radiographer may or may not be the same operator who then carries out the exposure. Both the radiologist and the radiographer must be appropriately entitled in their respective IR(ME)R duty holder roles by the employer to act within a defined scope of practice.

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 expected to do anything for which they are not entitled or trained.

Vetting

This term is commonly confused with justification; however, vetting may be separate activities that occur at different stages in the imaging pathway. The term vetting is not referred to in IR(ME)R and is not synonymous with the process of justification. Vetting is a term often used for those procedures that require a patient appointment, such as PET-CT scanning or fluoroscopic examinations, and is linked to the scheduling of an examination; however, this does not mean that the examination has been justified. It should be noted that, irrespective of the process used, all exposures must be justified by an appropriately trained and entitled practitioner before the exposure takes place. Vetting describes different activities for different imaging departments. It can describe, for example, booking/scheduling, setting protocols, justifying/authorising or reviewing previous imaging. If the term vetting is to be used it is important to clarify whether this refers to the justification, authorisation or protocolling of a referral. This should be clearly described in the employer's procedures.

It may be that more than one practitioner is responsible for the justification of different elements of an examination.

A referral for a CT scan of the head is reviewed by Radiologist A, who simultaneously justifies, authorises and protocols the scan. The patient is then booked onto a session supervised by a different radiologist (B). On attendance, the patient undergoes the CT scan as indicated by Radiologist A. On assessing the images acquired, Radiologist B, supervising the CT list, decides that a post-contrast CT scan of the same area is required, and this is justified and authorised by the supervising Radiologist B.

In this scenario, the reviewing radiologist (A) is the practitioner responsible for the justification of the pre-contrast scan. The supervising radiologist (B) is the practitioner responsible for the post-contrast scan. A clear record must be made of each practitioner's involvement in the justification of these scans.

A referral for a bone scintigram is justified and authorised by the licensed practitioner and protocolled for a planar acquisition. At imaging, an area is identified by the radiographer that would benefit from a SPECT-CT. The radiographer contacts the practitioner, who justifies and authorises the additional CT exposure.

Justification by practitioners working for third-party providers

Where an employer has contracted a third-party provider to deliver services (for example, justification and clinical evaluation), they should scrutinise and entitle a specified group of appropriately qualified and experienced individuals to act as practitioners to justify a predetermined group of examinations and operators for clinical evaluation.

The operator performing the examination must be able to identify the named individual who is the practitioner for each examination, prior to the exposure, and this information should be clearly documented.

The employer needs to be satisfied that all practitioners contracted to perform justification for its organisation are registered healthcare professionals and are trained and competent prior to entitling them as IR(ME)R practitioners.[10]

Justification of exposures to comforters and carers

Exposures to carers and comforters also require individual justification [Regulation 11(1)(b)]. Justification and authorisation may be carried out by a practitioner or these exposures may be authorised by an operator following authorisation guidelines.

Regulation 11(3)(b) specifies *additional* considerations that must be applied to the justification of exposures to carers or comforters. Where authorisation guidelines for carers and comforters are issued, the additional requirements of Regulation 11(3)(b) should be included as detailed in Table 7.2.

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 exposures to carers or comforters

IR(ME)R Regulation 11(3)(b)		Things to consider
(i)	**Any likely health benefits to the patient being examined**	▪ Possibility of having a diagnosis, treatment or knowing there is no underlying medical issue
(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 the examination 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 asymptomatic individuals (including health screening and individual health assessment)

Exposures may be performed for early detection of disease in a specific group of apparently healthy individuals who are considered to be at risk (for example, NHS Breast Screening Programme (NHSBSP)), or as part of an individual health assessment (IHA).[38] IHAs involve asymptomatic individuals who may consider they are at risk from disease and wish to exclude any unknown underlying health issues. IHAs are directed at individuals rather than groups or populations.

IR(ME)R [Regulation 11(3) (c)(i–iii)] has a number of requirements (in addition to those listed in Table 7.1) that must be considered when justifying exposures to asymptomatic individuals for early detection of disease. These include exposures undertaken as part of health screening programmes and IHAs. An example of good practice is where local procedures stipulate exposures to asymptomatic individuals are individually justified by the practitioner, rather than including this criteria in authorisation guidelines. The practitioner must take into account recommendations and guidance from relevant bodies. Examples include, but are not limited to, the NHSBSP and the Committee on Medical Aspects of Radiation in the Environment (COMARE).[39,40]

Justification for research exposures

All research exposures must be clearly identified, and each research trial must have ethics committee approval as described in Chapter 23 (Research). Each research exposure still requires individual justification and authorisation.

Justification for non-medical imaging exposures

An employer's procedure [Schedule 2(m)] is required for non-medical imaging exposures. Regulation 11(1)(e) requires that non-medical imaging exposures must comply with the employer's procedures for this group of exposures. The employer's procedure should specify which non-medical imaging exposures, if any, are undertaken by the organisation and how each group of non-medical exposures is identified and managed. Each non-medical exposure requires justification and authorisation taking into account the considerations detailed in Table 7.1. For example, it may be decided that only practitioners can justify non-medical referrals for legal purposes. Further information on non-medical imaging exposures can be found in Chapter 18 (Non-medical imaging exposures).

8. Optimisation

Optimisation is a key principle of the radiation protection framework within IR(ME)R. The optimisation process is the joint responsibility of the practitioner, operator and MPE. Requirements for optimisation of exposures are described in Regulation 12.

Regulation 12(1) states that 'the practitioner and operator ... must ensure that doses ... are kept ALARP consistent with the intended purpose'.

Regulation 14(3) requires the MPE to contribute to optimisation of exposures to individuals.

Optimisation requires a multidisciplinary team including MPEs, radiographers and radiologists. Optimisation is not limited to dose reduction; it requires an understanding of image quality, equipment parameters and their intercorrelation. The aim of optimisation is to achieve the image quality required to answer the clinical question using the lowest dose possible. Efficient working practices are important to ensure the team works effectively towards optimisation.

Review of optimisation should be carried out on a regular basis and when practice changes or when equipment is updated. The optimisation process should be considered and included in staff training. Table 8.1 describes areas for consideration when optimising exposures, but this list is not exhaustive.

Table 8.1: Things to consider when optimising exposures

Optimisation	Things to consider
Training **Regulation 17(1)**	▪ There is a robust training programme in place to ensure all practitioners and operators are competent and aware of how to use existing, new or updated equipment
Protocols **Regulation 6(4)**	▪ Written protocols are in place for all standard examinations, including non-medical imaging using medical radiological equipment
Quality assurance (QA) **Regulations 6(5), 12(3) and 15(1)**	▪ There are established QA programmes for both written procedures and equipment or methods.
Equipment **Regulation 12(3)**	▪ Existing equipment is appropriate for the individual examination and due consideration is given to ensuring each exposure is ALARP ▪ Review of DRLs
MPE advice **Regulations 14(2)(c) and 14(3)(a)**	▪ MPE to be consulted on optimisation, including patient dose assessment, radiation protection of patients and other individuals, and DRLs (Chapter 19)

Optimisation	Things to consider
Clinical audit **Regulation 7**	▪ How image quality, technique, protocols, doses or reject analysis may be audited and practice changed based on evidence
Carers and comforters **Regulation 6(6)**	▪ Adherence to dose constraints specified in employer's procedures

Regulation 12(8) requires the practitioner and operator to pay particular attention to the optimisation of the areas listed in Table 8.2.

Table 8.2: Areas requiring particular attention when optimising exposures

Particular attention when optimising	Examples of things to consider
Exposures of children	▪ Pre-programmed equipment settings (eg, based on a range of ages and weights) ▪ Specific paediatric imaging protocols for nuclear medicine, administered activity scaling and specify minimum activity
Exposures in a health screening programme	▪ Specific inclusion criteria for health screening programmes approved by the UK National Screening Committee (UK NSC) approved, robust QA programme, regular image quality audit, and so on to meet population screening programme standards
Exposures involving high doses (eg, fetal doses >10 mGy), examinations exceeding minimum threshold for tissue reactions (eg, cataracts, erythema), some hybrid imaging (eg, ^{18}FDG PET-CT), some CT interventional procedures	▪ Specialist training for staff involved in high-dose examinations ▪ Use of pre-programmed dose limit warnings ▪ Regular review of protocols ▪ Audit of image quality ▪ Dose surveys
Individuals where pregnancy cannot be excluded	▪ Minimise scan area to keep dose ALARP ▪ Referral pathway (eg, consultant to consultant) ▪ Administer a lower activity and increase image acquisition time

Particular attention when optimising	Examples of things to consider
Individuals who are breastfeeding	▪ Consider delaying examination; alternative radiopharmaceuticals; interruption of breast feeding

While standard protocols should be determined through an optimisation process, it is the responsibility of the operator to ensure exposure parameters are always appropriate for the individual. Technique and exposure parameters may require further optimisation from the planned protocol according to patient age, size or other pertinent clinical information.

Procedures with the potential to deliver high doses must be undertaken, or closely supervised, by operators who have specific training in those techniques. Dose limit warnings should be programmed into the equipment to ensure operators are aware that a high dose is being delivered. Dose limit warnings should be set in collaboration with the MPE and with consideration of average doses for different procedures.

Continuous review of optimisation of nuclear medicine protocols is considered good practice. Technologies such as resolution recovery should be considered and may be employed to reduce patient dose, improve image quality or improve patient experience through shorter acquisition times. A multidisciplinary approach should be taken in the optimisation process in order to produce diagnostic images at the lowest practicable dose.

9. Diagnostic reference levels

Diagnostic reference levels (DRLs) are radiation dose levels, or for nuclear medicine the administered activity, for typical diagnostic examinations on standard size adults and children for broadly defined types of equipment (for example, CT, fluoroscopy or general radiography) [Regulation 2(1)].

DRLs are benchmarks of patient radiation dose, based on dose indices and where certain variables, such as equipment type, examination and patient size, are standardised to minimise uncertainty. DRLs are often considered the first step in the optimisation process.

DRLs should not be consistently exceeded when good and normal practice is applied. DRLs should be used with professional judgement. All operators should be familiar with and trained in the appropriate use of DRLs.

In diagnostic imaging and interventional radiology, DRLs are generally set as a result of national and local surveys (referred to respectively as national DRLs or local DRLs). DRLs apply to a population, and individual patients should not be compared with the DRL, nor should DRLs be used as dose limits. Instead, DRLs are an essential tool in the optimisation process.[41] They can help to identify issues relating to equipment or practice by highlighting unusually high or low radiation doses.

DRLs are given as dose indices, in units relevant for the imaging modality. Appropriate dose parameters for DRLs are adopted for each imaging modality, as shown in Table 9.1.

Table 9.1: Examples of DRL dose indices

Modality	DRL	Example units
General radiography (digital radiography, computed radiography)	Dose area product (DAP)	$Gy.cm^2$
Fluoroscopy, including interventional	Fluoroscopy DAP Acquisition DAP	$Gy.cm^2$ $Gy.cm^2$
CT	Computed tomography dose index (CTDIvol) Dose length product (DLP)	mGy mGy.cm
Mammography	Mean glandular dose (MGD)	mGy
Nuclear medicine	Administered activity	MBq

DRLs are applicable for standard size individuals, unless stated otherwise, and relate to the imaged body region and the specific diagnostic question or clinical indication. If comparing DRLs from different populations, variations in standard size should be taken into account. However, for ease of data collection, and to minimise uncertainties where the number of contributions is small, a default approach is to use 70 kg for adults (+/– 5 kg when presented as a mean or median value, or +/– 20 kg for individual contributions to a mean or median value), even though this does not account for current, regional or clinical demographics.

Paediatric populations vary and DRLs will need to take into account a range of ages and weights. Weight is generally considered as the easiest approach for establishing paediatric body DRLs, although age is sufficient for paediatric heads.[42] Further guidance on establishing paediatric DRLs is available from this reference.

In nuclear medicine, the DRL is the administered activity. Nuclear medicine protocols should specify a tolerance on the activity to be administered (for example, +/−10%) for each examination. For some nuclear medicine examinations (for example, myocardial perfusion scanning or PET-CT), local DRLs may use weight-based activity schedules; this should be included in the protocols.

Regulation 6(5)(c)(i–iii) says that the employer must establish DRLs for exposures for typical examinations carried out as part of medical diagnosis or treatment at that centre. This includes procedures as part of health screening programmes, for asymptomatic individuals and, where practicable, for non-medical imaging using medical radiological equipment. If a department performs an adequate number of standard interventional procedures, a DRL for those procedures should be established. Local DRLs should be set with regard to national and European DRLs where available.

National DRLs (NDRLs)

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

NDRLs in computed tomography (including CT in hybrid imaging), planar diagnostic X-ray, non-complex interventional and dental radiography, fluoroscopy and mammography are set using data submitted by hospitals to national dose surveys. These national dose surveys or audits may be undertaken by PHE, professional bodies or other suitable organisations.[43] Resultant data, suitable as NDRLs, are presented to the NDRL Working Party for their consideration.

The NDRL for the majority of these modalities is set as the third quartile of the national survey, meaning that three-quarters of submissions have values below the NDRL, and one quarter above. The exception is the NDRL for screening mammography, which is set as an upper limit from a national survey.

NDRLs for administered radioactivity in nuclear medicine examinations are set by the Administration of Radioactive Substances Advisory Committee (ARSAC).[21] These are the recommended administered activities for standard size patients.

Local DRLs (LDRLs)

Regulation 14(3)(a) requires the MPE to contribute to the application and use of DRLs. Regular dose audits should be carried out under a local governance programme, when new equipment is installed and if clinical practice changes, as advised in IPEM guidance.[44] This is most effective when undertaken with advice from the MPE working as part of a multidisciplinary team including radiographers, radiologists, interventionists and cardiologists. LDRLs should reflect local practice, equipment and patient cohorts. Consideration should be given to setting LDRLs for children for commonly requested examinations. The employer's procedure [Schedule 2(f)] should detail actions required where LDRLs are consistently exceeded [Regulation 6(7)].

An employer, with advice from their MPE and a multidisciplinary team, may decide to adopt NDRLs as their own LDRLs or, following local dose audits, choose to set their own LDRLs. An LDRL should be appropriately set using values from a local dose audit, with an appropriate action level identified.[44] Where an LDRL is set higher than the NDRL, based on a local dose audit, this should be justified by the employer.[44] Efforts should be made to optimise further, or consideration given to replacement of equipment. Having the LDRLs displayed in the work area is considered good practice.

A radiology department has recently installed a new CR chest X-ray room. As part of the dose audit schedule, the lead radiographer and MPE work together to analyse dose information recorded on the RIS system from this room over a six-month period. The data is used to establish an LDRL for both adult and paediatric chest X-ray examinations using the employer's agreed method. Once the LDRLs are established, they are compared with NDRLs before being ratified by the radiation protection committee. The room DRL chart is updated to reflect the newly agreed values and staff are informed of the change.

In nuclear medicine, it may be possible to set an LDRL at a lower administered activity than the NDRL. These LDRLs may be exceeded in exceptional circumstances, such as with a bariatric patient or a patient who is unable to tolerate standard acquisition times. Where administered activity is increased based on an individual's clinical circumstances, this must be justified and recorded by the licensed practitioner. Further guidance is available from ARSAC.[21]

A nuclear cardiology department has set an LDRL of 600MBq +/– 10% for a two-day myocardial perfusion imaging protocol using ^{99m}Tc tetrofosmin. An audit of administered activities from the last six months shows that the distribution is skewed towards the upper limit of the tolerance range with the average activity administered 635MBq. The MPE is contacted and further analysis of the administered activity is carried out including assessment of residual activity, correlation with patient weight and assessment of image quality. Following this analysis, a weight-based activity schedule is proposed and ratified by the radiation protection committee.

LDRLs should be established for the CT component of hybrid imaging. LDRLs will vary depending on how the CT component is used, and the purpose of the exposure should be clear. If localisation is the aim rather than requiring diagnostic information, a low dose DRL should be established. Where diagnostic information is required (for example, in parathyroid imaging), a high-dose exposure is likely to be used to provide detailed diagnostic images of the parathyroid glands. When setting LDRLs it is important to engage MPEs in both CT and nuclear medicine to ensure both elements of the exposure are optimised.

Image optimisation teams (IOT)

DRLs should be reviewed systematically, preferably by a multidisciplinary team consisting of radiographers, radiologists, interventionists and MPEs. This function may be undertaken by the IOT where doses, protocols and processes can be reviewed in a structured way. A formal record of IOT meetings will ensure any actions are expedited and followed up.[16]

An X-ray department has a dedicated cardiology interventional suite where many specialist cardiac examinations are undertaken each year. There are no NDRLs for these particular specialist procedures as there is a lack of available data. The department, however, has analysed and reviewed dose data for the procedures they have carried out and established LDRLs for their typical examinations and patient sizes at this department. Future reviews of patient doses can be undertaken which compare doses with the LDRLs to inform optimisation. This review of doses involves a multidisciplinary team including radiographers, interventionists and MPEs.

10. Patient dose assessment and recording

IR(ME)R may require individual doses to be reviewed and assessed when:

- Establishing local diagnostic reference levels (LDRLs)
- Undertaking incident analysis following, for example, equipment malfunction
- Comparing and standardising protocols between equipment
- Performing clinical audit
- Collecting dose estimates as required under Regulation 13
- Optimising protocols
- Establishing dose constraints.

The best method by which this can be achieved is to record parameters relevant to each exposure. The parameters to be recorded can be found in Chapter 9 (DRLs).

There are many methods by which dose data can be recorded, such as dose management systems, RIS, patient information systems, local data files such as Microsoft Excel, or by maintaining paper records. If the data are recorded in a single place, subsequent review of the data is much easier as it avoids having to convert data from paper files or individual patient records.

There is a requirement for an employer's procedure for the assessment of patient dose [Schedule 2(e)]. The employer's procedure should specify what information needs to be recorded as 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. Operators must be aware of the dose indicator units of each system and ensure they are recorded according to the employer's procedures. The employer must seek advice from the MPE about the most appropriate methods for recording and assessing the patient dose taking into account the systems in place. Regulation 14(2)(d) requires the MPE to give advice on patient dosimetry.

Where high-dose examinations are conducted, the employer's procedure should describe the process for recording and investigating cases where doses exceed a threshold trigger level, above which deterministic effects could occur. This trigger level could be based on an appropriate dose indicator such as dose area product (DAP) or dose length product (DLP). Facilities for dose mapping significantly improve the ability to identify such cases and may be available on new equipment. The departmental procedure should include a process for the clinical follow-up of cases where the patient has received a dose that could lead to potential tissue reactions. As part of the consent process, the operator should discuss the benefits and risks of the exposure, including the radiation effects that may occur. More information is included in Chapter 14 (Communicating benefits and risks).

Regulation 15(5) requires that any interventional radiology and CT equipment must be able to provide the appropriate information to make an assessment of the dose at the end of an exposure. Further details are included in Chapter 20 (Equipment and quality assurance).

Table 10.1 describes the dose recording requirements in Regulation 16 for equipment installed after 6 February 2018.

Table 10.1: IR(ME)R requirements for equipment installed after 6 February 2018

Equipment installed	Requirement
Interventional radiology equipment **Regulation 16(3)**	Device to inform those staff involved of the amount of radiation produced during the exposure
Interventional and CT equipment **Regulation 16(5)**	Must be able to transfer dose information to the individual's record, such as the radiology information system (RIS) or picture archiving and communications system (PACS)
Any other equipment producing ionising radiation for medical or non-medical purposes **Regulations 16(6)(a), 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

Generally, equipment will display a dose indicator, which is dependent on the modality; this must be recorded on the patient record or referral and is also available within the digital imaging and communications in medicine (DICOM) header of the image when stored on the PACS. To facilitate dose and DRL data collection, individual doses should also be recorded on the RIS. In paediatric examinations, it may be helpful to record the weight of the individual for inclusion in dose audits. Dose management software may be used for optimisation purposes.

11. Clinical evaluation

Regulation 12(9) says that the employer must ensure that a clinical evaluation of the outcome is recorded for each exposure. Clinical evaluation involves the assessment of an image and the documentation by suitably trained and entitled operators. Clinical evaluation is most commonly considered to be a documented radiology report, which is usually recorded on the RIS. Other methods of clinical evaluation include written records in the patient notes or quantification data from non-imaging nuclear medicine examinations.

Any assessment of an image that has an impact on patient management should also be considered a clinical evaluation. There are a number of areas within an organisation where clinical evaluation is performed and recorded. For example, radiographers alerting referrers to a significant finding,[45] orthopaedic surgeons using fluoroscopic guidance in theatre, cardiologists performing interventional procedures or clinical technologists processing dynamic images in nuclear medicine. In some of these instances, the outcome of the clinical evaluation may be recorded directly in the patient's clinical notes.

The different processes for recording clinical evaluation should be clearly described in the employer's procedure [Schedule 2(j)]. The procedure should explain how and where each clinical evaluation is recorded and describe when, or if, exposure factors should be included. Exposure factors do not always form part of the formal report but are routinely recorded on the RIS or dose management software, either by the operator or by being automatically transferred. The procedure should also apply to those exposures that take place outside of the diagnostic imaging, interventional radiology and nuclear medicine departments. All staff undertaking clinical evaluation, including those working in departments remote from radiology, must be trained and entitled and must follow the employer's procedure.

A clinical evaluation is not required for individuals who are exposed while being a carer or comforter.

Clinical evaluation is an operator function. Each individual or group of individuals who undertake this task must be entitled in accordance with the relevant employer's procedure [Schedule 2(b)] following adequate training and assessment of competency.

The process of clinical evaluation, and adherence to the employer's procedure, should be assessed by audit (see Chapter 3 (Audit)).[46] Clinical evaluation is the final step in the justification process. Exposures that are not clinically evaluated are not justified.

A mobile chest X-ray is performed on a patient in an intensive care unit (ICU) following insertion of a central venous pressure (CVP) line. To effectively manage patient treatment the image is clinically evaluated, on the unit, by a suitably trained and entitled ICU clinician. The evaluation confirms the line is appropriately positioned for immediate use. This evaluation is documented in the patient's notes by the clinician.

An orthopaedic surgeon performing a hip-pinning procedure in theatre uses fluoroscopic guidance to accurately position the pins. Following completion of the operation, the surgeon records the clinical evaluation in the patient's postoperative notes. The radiographer present during the procedure records dose-related factors on the RIS. The radiology department performs a regular audit of patient notes to monitor whether the clinical evaluation process is completed in accordance with the employer's procedure.

The RCR has produced standards for the reporting of imaging investigations by non-radiologist medically qualified practitioners.[47]

Where an employer contracts with a third party to provide a clinical evaluation service it should consider the following:

- Evidence that staff providing any clinical evaluation are trained, competent and entitled to do so
- Evidence required to ensure robust data confidentiality systems are in place (for example, GDPR)
- Communication system for discussion of findings, including an escalation procedure for urgent clinical findings
- Audit programme.

Guidance is available from the RCR on standards for the provision of teleradiology, including specific standards for reporting and communication of results.[48]

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 should specify how and when an individual is to be identified.

Correct identification (ID) of the patient or individual to be exposed is an operator task and must be undertaken prior to any exposure. Correct identification always starts with the referrer. There is evidence to show that incidents involving referral of the wrong patient are among the largest percentage of all diagnostic errors notified to the IR(ME)R regulators.[36] Further information on accidental and unintended exposures is included in Chapter 21 (Accidental or unintended exposures).

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.

For the majority of requested examinations, the most appropriate and adequate means of positively confirming the identification of the individual is by direct questioning requiring an active response. A minimum of three questions should be asked, typically:

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

All responses must match the information provided on the referral. The employer's procedure must describe the process to follow where there are discrepancies.

Professional body guidance and resources are available to assist organisations to implement robust policies for the process of identification.[49] There are a number of additional checking processes suggested by professional bodies such as, but not limited to, checking previous imaging and confirming laterality/anatomy.[50,51] The introduction of the WHO checklist in 2008 has been shown to reduce the number of deaths related to surgical processes and is endorsed by the RCR in its guidance on implementing safety checklists for radiological procedures.[51–53]

The operator undertaking the individual identification check must be identifiable by their signature on the referral or electronically on the RIS. The employer's procedure should state where this should be recorded and define the responsibilities of each operator involved. Where possible, the same operator performing the exposure should confirm the individual's identification. Where there are multiple operators involved in the exposure, the operator performing the identification should clearly communicate and cross-check the individual's identification with the operator undertaking the exposure. The employer's procedure must describe the responsibilities of the duty holders in this two-stage process.

There may be circumstances where verbal communication is difficult or not possible. It is important that the employer's procedure identifies alternative means of establishing the correct identity of the individual. Some examples of how this could be achieved are included in Table 12.1.

Table 12.1: Alternative methods of identification

Scenario	Things to consider
Unconscious individual/ patient	▪ Use hospital wristband as part of ID check ▪ Cross-reference hospital 'unknown patient' number and major incident policies ▪ Use national unique patient identification number ▪ Can a relative, carer or staff member confirm the individual's ID?
A patient undergoing an interventional diagnostic or surgical procedure	▪ Who confirms the identification of the patient (eg, anaesthetist, nurse in charge, surgeon)? ▪ Use of the WHO surgical checklist[51]
An individual who is lacking capacity to identify themselves	▪ Use hospital wristband to confirm ID ▪ Can a relative, carer or staff member confirm the individual's ID?
An individual with sensory impairment (eg, deaf or blind)	▪ Confirm ID using written cards, braille or sign language to assist active process ▪ Could other forms of ID be used (eg, photo ID driving licence)?
An individual who speaks an alternative language	▪ Local policy for the provision of a translation service ▪ Hospitals may require their own interpreter to be present 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
Immigration cases	▪ May be more complex identifying the individual and may require completion of additional documentation according to local procedure

IR(ME)R Schedule 3 (Adequate Training) includes the identification of the individual being exposed as a requirement, and training on this topic must be completed before operators are entitled.

In nuclear medicine, the employer's procedure should specify how the correct radiopharmaceutical is identified, including labelling requirements.

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. IR(ME)R includes the requirement to make enquiries of individuals of childbearing potential, and this should accurately reflect the diversity of the gender spectrum in the population.

There is an increased risk of detrimental effects from radiation exposure upon the rapidly growing and dividing cells of a fetus compared with an adult. Employers must have a procedure to establish pregnancy and breastfeeding status [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 inclusion in the employer's procedure

Regulation	Things to consider
Procedure to establish pregnancy and breastfeeding status **Schedule 2(c)**	▪ Examinations where pregnancy enquiries are relevant (eg, primary beam between diaphragm and knees, and all nuclear medicine examinations) ▪ Age range based on local demographics ▪ High-dose and low-dose examinations ▪ Process if more than one operator is involved in an exposure ▪ Process for patients in theatres ▪ Unconscious patients and emergency situations ▪ Individuals lacking capacity and those with sensory impairment (eg, deaf or blind) ▪ Process for the exposure of pregnant individuals ▪ Process when pregnancy is disclosed in individuals aged under 16 (including support and safeguarding where appropriate*) ▪ Process to follow if pregnancy testing is part of the local decision-making process ▪ Exceptions where pregnancy checking is not required
Measures to raise awareness **Regulation 6(8)**	▪ Posters in waiting areas ▪ Information in appointment letters and documentation for wards ▪ Adequate training for those involved with patient communication

Regulation	Things to consider
Justification **Regulation 11**	▪ Alternative examination involving less or no ionising radiation ▪ Urgency of the examination and whether it could be delayed ▪ Consultant-to-consultant referral
Optimisation **Regulation 12**	▪ Optimised protocols for pregnant individuals ▪ Reduce administered activity and image for longer where possible ▪ 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.[54,55]

Making pregnancy or breastfeeding enquiries in advance of an exposure is an operator task; however, the referrer is responsible for providing sufficient medical data to enable the practitioner to justify the exposure [Regulation (10)(5)]. This data should include previous diagnostic information and the pregnancy status of the individual. Where 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), bilateral salpingo-oophorectomy, sterilisation). Regulation 11(1)(f) requires operators to enquire about pregnancy status where relevant. Therefore, 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 procedure. For example:

- 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.
- Enquiries about the possibility of pregnancy may be considered relevant for all individuals aged between the locally agreed age range who are undergoing exposures of the abdomen and pelvis or any high-dose or interventional exposures.
- It may be considered not relevant to ask an individual who is known to have had a TAH or who is undergoing medical treatment resulting in infertility or arrested ovulation about any possibility of pregnancy.

Wherever possible, any appointment information sent out prior to the examination 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 (where appropriate), is essential [Regulation 6(8)].

Employer's procedure

Age range

In many departments, pregnancy enquiries are made for examinations 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).

Establishing pregnancy status can be a sensitive matter, especially, for example, when asking those under the age of 16 years accompanied by a parent. The privacy and dignity of the individual should be respected when considering where and how these personal conversations occur and with whom the information is shared.

Further information that may be of assistance when developing an employer's procedure is available from the Society and College of Radiographers and the Royal College of Paediatrics and Child Health.[56,57]

Unconscious, anaesthetised or sedated patients and emergency situations

The employer's procedure must specify whose responsibility it is to confirm pregnancy status prior to the patient being anaesthetised or sedated. Interventional procedures may include the use of additional documentation such as the WHO checklist.[58]

NICE clinical guideline 45 'Routine preoperative tests for elective surgery' recommends enquiring about the possibility of pregnancy, providing information relating to the risks to the fetus, documenting conversations and carrying out a pregnancy test, with consent, if there is any doubt.[59]

Emergency examinations do not preclude the necessity to check for the possibility of pregnancy, unless the individual's care would be put at risk by doing so. These situations should be anticipated and clearly described in the employer's procedure. The procedure should clearly define the mechanism for justification of the exposure in these circumstances.

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.

The legal process for gender change is in the Gender Recognition Act 2004 (GRA 2004).[60] The Equality Act 2010 (EA 2010) safeguards individuals with a protected characteristic from discrimination and harassment.[61] Gender reassignment is a protected characteristic and a person who is proposing to undergo or is undergoing gender reassignment is protected from discrimination.

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.[56] 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 an X-ray'.[62,63]

The GRA 2004 prohibits the disclosure without consent of protected information about a person who has changed their gender. The referrer may not be able to provide information on pregnancy status when there is a need to protect the confidentiality of a person's transitional status. The individual must consent to this information being shared.

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. 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
Underage sexual activity	▪ Legal consequences for those under 16 years (safeguarding process)
Concealed pregnancy	▪ Vulnerable individuals (eg, possibility of sexual abuse)

Scenario	Additional things to consider
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

Breastfeeding

Individuals who are breastfeeding and require a nuclear medicine study need to be advised of the risks to themselves and their baby. If they decide to proceed with the study, consideration should be given to:

- Delaying the test until they are no longer breastfeeding
- Choosing an alternative radiopharmaceutical that is not secreted in breast milk
- Ensuring the purity of the radiotracer.

Where the administration goes ahead, ARSAC guidance on breastfeeding interruption times should be consulted with the aim of keeping the dose to the baby below 1mSv.[21]

Practical application

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.

Examinations considered to be high dose, resulting in fetal doses of more than about 10mGy, should be scheduled within the first ten days of the individual's menstrual cycle (ten-day rule). It is unlikely that an individual will become pregnant within the first ten days following the start of a period. The employer's procedures should clearly define the examinations classed as high dose, where the ten-day rule should be used. Further information has been produced jointly by the Health Protection Agency, the RCR and the SCoR.[64]

An example of a pregnancy enquiries flow chart can be found in Appendix 7.

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 should be noted that where there is no appropriate imaging alternative, an exposure may be justified even when it is known the individual is or may be pregnant. A possible example of this is in the case of major trauma. However, in all cases there is a requirement to follow procedures. A specific procedure should be considered for the justification of exposures during pregnancy, for example consultant-to-consultant referral.

Table 13.3: Possible actions to consider

Response	Possible action
No	▪ Proceed with the examination
Yes	▪ Consider deferring the examination if not urgent ▪ Consider another examination that involves less or no ionising radiation ▪ Operator to discuss the examination with a practitioner and possibly an MPE to agree whether the exposure could be further optimised, taking into consideration the potential exposure of the fetus ▪ Confirm the exposure is still justified and discuss with the referrer if it can be deferred
Not sure	▪ Determine whether the individual's period is overdue ▪ Consider deferring the examination if not urgent ▪ If their period is not overdue then continue with the examination unless it is a high-dose examination (see below) ▪ If their period is overdue, or they report a missed period, they should be considered pregnant ▪ Consider another examination that involves less or no ionising radiation ▪ Consider the use of an appropriate pregnancy test taking into account the radiation 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, the training required to perform the test and deliver the results, and the facilities (including time) required to do so; guidance is available on the use and accuracy of pregnancy testing[57,59,65,66]

If the possibility of pregnancy is discovered before the exposure takes place, the operator should alert the practitioner, who should reconsider justification of the exposure. The practitioner may recommend delaying the exposure or suggest an alternative imaging pathway.

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.[67] IR(ME)R applies to all individuals of childbearing potential.

14. Communicating benefits and risks

Communicating the benefits and risks associated with an ionising radiation exposure has always been recognised as a fundamental principle of diagnostic imaging, interventional radiology and nuclear medicine services. In normal daily practice, duty holders have conversations with patients with the intention of improving understanding of the benefits of having the examination 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.[68] Therefore, it is important to ensure that the benefits of the exposure are clearly described along with the implications of not having the examination. IR(ME)R duty holders may wish to reference the justification process, emphasising that the examination is the most appropriate option to answer the clinical question posed, has been tailored to the individual and that radiation doses are optimised.

Information may be provided by a combination of IR(ME)R duty holders, such as referrer, practitioner or operator, or it may fall to only one duty holder. The employer's procedure should specify 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 examination they are being offered.

The way in which this information is delivered will vary depending on the type of examination, the individual being exposed, the diverse delivery of service provision, and so on. The information can take various forms, such as posters,[69] leaflets, verbal discussions and appointment letters, or be part of written consent.

The employer's procedure should outline a range of scenarios where different types of information are provided. The method of communication and level of information provided may vary depending on the complexity of the examination and the level of risk.[70]

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.[71,72] 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 consistent message ▪ Patient dignity, when choosing the location for discussion ▪ Sufficient time for questions ▪ Availability of additional advice (eg, MPE)
Poster	▪ Content of information ▪ Placement and visibility of poster ▪ Size of poster ▪ Alternative languages ▪ Invitation to discuss any concerns or request more information
Appointment letter/ information leaflet	▪ Use of standard phrases to ensure consistent message ▪ Invitation to discuss any concerns or request more information
Written consent	▪ Incorporation into the consent process for the examination (eg, interventional/cardiology, theatres, CT colonography)

The use of risk bands and ranges in Table 14.2 may help explain to the individual the level of risk of cancer induction associated with the examination.[73] It may be helpful for the employer's procedure to include simple phrases as examples for communicating this information to the individual. Comparisons to natural background radiation exposure may be considered as part of the approach to understanding risks.[74] However, this concept may not be familiar to everyone and may result in further questions. Natural background radiation involves whole-body exposure, while diagnostic imaging exposures are more localised.

Table 14.2: Examples of X-ray examinations divided into four broad risk bands for cancer induction patients aged 30–60 years[73]

Risk band	Risk range	Typical type of X-ray examination
Negligible	<1 in a million	Radiography of chest, limbs and teeth
Minimal	1 in a million to 1 in 100,000	Radiography of head, neck and joints
Very low	1 in 100,000 to 1 in 10,000	Radiography of spine, abdomen and pelvis
Low	1 in 10,000 to 1 in 1,000	CT, angiography studies of the alimentary, biliary and urinary tracts, and interventional radiology

Perceptions of 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, avoid medical jargon, speak in a concise manner and make sure the information being given is understood. The individuals should be given the opportunity to ask questions if they have concerns about the information being provided.

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 RIS, a consent form or the medical notes).

A pregnant woman arrives in the CT unit from the emergency department with a suspected pulmonary embolism. The referring consultant discusses the patient with the CT radiologist and they agree that the most appropriate examination due to the level of urgency is a CT pulmonary angiogram. The referring consultant explains to the patient the benefits of having the examination and associated low risk to both her and her unborn child.

The patient is very unwell but is also distressed and worried about the risk from the radiation to her unborn child and requests further information.

The radiologist justifying the referral explains in detail to the patient the benefits of having the examination, the associated low risk from the exposure to her and her unborn child, how the examination is optimised and the risk of not performing the examination. The patient agrees to undergo the examination and signs the appropriate documentation. The radiologist makes a record of the discussions on the RIS.

Table 14.3 includes additional situations for inclusion in the employer's procedure.

Table 14.3: Additional situations for inclusion in employer's procedure

Example situations for inclusion in employer's procedure	Things to consider
Emergency trauma unconscious patient	▪ No information provided to the individual
Paediatric patients	▪ Information provided to parent/ guardian
Additional advice is required	▪ Contact details for support (eg, radiologist or MPE)
Patient lacks capacity	▪ Information provided to representative
Patient with sensory impairment	▪ Additional tools
Communication in alternative languages for local population demographics	▪ Information leaflets in different languages ▪ How to contact an interpreter

Regulation 12(6) requires, where appropriate, written instructions and information to be given to patients (or their representatives) who are administered 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 should be used to inform the advice and written information given to patients.

The written information should:

- Provide advice on precautions to observe after the exposure to restrict the dose to others the patient may come into contact with
- Describe the risks from the exposure to other people
- Be provided before the patient leaves the hospital
- Include contact details for obtaining further information, such as the MPE.

In practice, written information leaflets are often sent to patients with their appointment letters, including details of how to get further information.

15. Children and young people

While not defined in IR(ME)R a child is generally identified as a person under the age of 18. Different services may have different age cut-off points at an operational or service level. 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.[75]

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.

Children carry greater risk of radiation-induced injury than adults, especially younger children and girls. The benefits of a diagnosis should be considered in conjunction with the increased risk to the child from ionising radiation, due to the rapidly growing and dividing cells of children.

Regulation 11(1)(b) describes how all exposures must be justified to give sufficient net benefit. Regulation 11(2)(a) requires that the specific objectives of the exposure and the characteristics of the individual must be taken into consideration by the practitioner when justifying any exposure. Practitioners must be aware of the normal variations of growth and development and where conditions are restricted to childhood or present themselves differently to that of adults.[76]

Consideration should also be given to alternative techniques that do not use ionising radiation, such as the use of ultrasound as a primary imaging modality for children to answer the clinical question of abdominal pain.

Therefore, specific medical conditions in childhood are not necessarily investigated and managed in the same way as for adults. Some examples are:

- The investigation of developmental dysplasia of the hip (DDH)[77]
- Suspected physical abuse (SPA), previously referred to as non-accidental injury (NAI)[78]
- Imaging of the chest for suspected infection; there are fewer indications for initial imaging and follow-up in children (due to the different course and pattern of risk for the child with chest infections)
- Imaging trauma in children.[79]

When considering referrals for paediatric imaging, the justification process and protocols used for adults may not necessarily be appropriate. Paediatric referral guidelines are available.[31] Where a practitioner issues authorisation guidelines, they should include specific paediatric criteria to enable operators to authorise these referrals.

Imaging children poses distinct challenges.[80] In certain circumstances, paediatric examinations may have a better outcome if the child is supported by someone they know. These individuals should be designated as a carer and comforter, and further information is available in Chapter 16 (Carers and comforters). When providing an effective and quality paediatric imaging service, consideration should be given to offering specific child-friendly X-ray rooms. The room should be equipped with the necessary accessory equipment such as immobilisation devices and, where possible, items for distracting the child during the examination, such as toys, colourful lights or electronic devices.

It is important when imaging children that equipment used has the full range of dose reduction features and, where possible, a broad selection of pre-programmed exposure factors based on a range of ages or weights.[16] Advice from MPEs should be sought to assist in optimising protocols to ensure doses are kept ALARP. LDRLs should be established for routine paediatric examinations, and where this is not possible, national or European paediatric DRLs should be made available to staff.[43]

While patient anxiety, fear, lack of co-operation and inability to keep still are not exclusive to childhood, the likelihood of practical difficulties in obtaining a radiological examination is much greater.[81] Experience and expertise are required when imaging the young.[82] Gaining the trust and co-operation of the child, with clear communication between the operator and both the child and parent/guardian, will improve the probability of getting successful and adequate diagnostic images first time.

To minimise the need for sedation, distraction strategies should be considered and, where available, the involvement of play specialists. Additional considerations for optimising paediatric exposures are included in Table 15.1.

Table 15.1: Things to consider when optimising paediatric exposures

Requirements	Things to consider
Attention to optimisation of paediatric exposures **Regulation 12(8)**	▪ Effective immobilisation ▪ Collimation (rather than post-process image cropping) ▪ Appropriate use of grids, focal spot selection, AEC, and so on ▪ Pre-programmed exposure factors on all X-ray equipment ▪ Use and development of paediatric exposure charts (age and size specific)
Adequate training **Regulation 17(1)**	▪ Specialist training programmes for operators and practitioners
Co-operation with other specialists involved **Regulation 10(6)**	▪ MPE involvement in paediatric protocol development ▪ Sharing of relevant information ▪ Multidisciplinary team meetings
Carers and comforters **Regulation 6(6)**	▪ Adherence to dose constraints specified in employer's procedures

Having specific paediatric protocols will support the operator in limiting the number of views/phases; for example, a single AP projection for the investigation of DDH or single-phase scanning for body imaging in CT. Consideration should also be given to image quality and possible acceptance of noisier images if they will provide sufficient diagnostic information for a lower dose of radiation.

Professional bodies and employers should continue to provide opportunities for staff to receive continuous professional development and specialist training in paediatric imaging.[82]

Emphasis should be placed on the appropriate use of high-dose examinations for children such as CT or PET-CT, with a multidisciplinary approach to optimisation though groups such as IOTs.[16]

Concerning nuclear medicine studies, it is important to liaise with parents/guardians in advance of the scan to provide information and understand the child's needs and requirements. There should be consideration of whether sedation is required and whether there are appropriate facilities for this locally.[83] It is best practice to have a paediatric cannulation service to enhance patient experience. Nuclear medicine and PET-CT departments designed for adults often provide a poor environment for children, but a few simple modifications and the involvement of play specialists can make a marked improvement. Separate imaging protocols should be established for paediatric imaging; these should be optimised and administered activity calculated according to the employer's procedures. Minimum administered activity values should be established. Paediatric hybrid imaging protocols should also consider optimisation of the CT imaging. Guidance is available from ARSAC and European Association of Nuclear Medicine (EANM).[21,84]

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 individual 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 or Macmillan nurses) should be considered under the Ionising Radiations Regulations 2017.[85]

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 when 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.

The radiation risk assessment for the examination should be used to identify standard radiation protection precautions and any potential restrictions for nuclear medicine procedures. Typical dose estimates and radiation protection precautions may be based on published data.[86] Where, due to the level of support and care provided, individuals cannot comply with any precautions identified by the radiation risk assessment, they may need to be designated as a carer and comforter. For clarity, 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 (for example, a friend driving a nuclear medicine patient home from hospital).

A person may be designated as a carer and comforter where they attend with an individual 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 with a patient in an X-ray room, gamma camera room or PET-CT scanner room ▪ Being present in the injection room during the administration of radioactive substances or staying with the patient during the uptake phase of a PET-CT scan

Criteria	Examples
Individuals who provide support or care to those who have been administered radioactive substances and are not able or willing to follow the usual instructions regarding prolonged close contact **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 to follow usual radiation protection precautions: ▪ Particularly relevant for molecular radiotherapy where restrictions such as sleeping apart for a period of time are often given; a radiation risk assessment must be carried out

The employer's procedure may consider scenarios where the justification of the dose to the carer and comforter may require particular attention, additional radiation protection advice from the MPE and a lower dose constraint. 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 in authorisation guidelines).

Normally, individuals who do not attend with the patient cannot 'knowingly and willingly' incur an exposure and therefore should be treated as members of the public. Guidance is available on dose limits and setting dose constraints for members of the public.[87] However, there are certain exposures, such as those arising from nuclear medicine or PET procedures, where 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 molecular radiotherapy, where close contact restrictions are often given. Where this situation is anticipated, the process should be described in the employer's procedure and appropriately documented.

Regulation 19 provides a defence of due diligence. 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.

A two-year-old child requires a dimercaptosuccinic acid (DMSA) examination. The child is accompanied by their father to the hospital. Prior to the exposure taking place, the clinical technologist explains the procedure and discusses the exposure that the father will receive in supporting his child during the examination. The child's father is happy to go ahead, and the clinical technologist authorises the exposure to the father as a carer and comforter following authorisation guidelines.

On departure from hospital, the father is given written information to observe careful hygiene when changing the child's nappies. On return home, the child is cared for by the mother for the rest of the day. The mother cannot be designated as a carer and comforter as she has not been given the opportunity to 'knowingly and willingly' consent to the exposure. In this situation, the mother will receive a very low exposure, and for radiation protection purposes, she is considered to be a member of the public. The written information given under Regulation 12(6) provides advice for keeping the dose to the child's mother ALARP.

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 operator following authorisation guidelines, as seen in Chapter 7 (Justification and authorisation). The person who acts as practitioner or authorising operator for an exposure to a carer and comforter is the person best placed to do this. This might not be the person who initially justifies and authorises the exposure. 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 16.2 [Regulation 11(2)]. Additional considerations must be applied to the justification of exposures to carers or comforters as detailed in Table 16.3 [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 16.2 and Table 16.3 must be considered when justifying exposures to carers or comforters.

Table 16.2: Considerations for justification of an exposure

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? ▪ Previous imaging, medical history, age, pregnancy or breastfeeding status, body habitus ▪ For nuclear medicine 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 investigation
(b)	**The total potential diagnostic or therapeutic benefits to the individual and society from the exposure**	▪ What is the expected benefit of the exposure? ▪ Is the exposure likely to answer the clinical question? ▪ Will the individual's treatment be altered?
(c)	**The detriment the exposure may cause**	▪ What is the likely dose from the exposure? ▪ What is the risk to the individual from that dose? ▪ Nuclear medicine patients with caring responsibilities, those who are hospital inpatients and those who may have close contact with other people after the investigation may require additional radiation protection advice ▪ Potential exposure to carers and comforters
(d)	**What alternative imaging modalities are available that could answer the diagnostic question but involve less or no radiation?**	▪ How effective are any alternative techniques compared with the planned exposure? ▪ Is the alternative available locally in a clinically acceptable timeframe?

Table 16.3: Additional considerations for justification of exposures to carers or comforters

Regulation 11(3)(b)		Things to consider
(i)	**Any likely health benefits to the patient being examined**	▪ Possibility of having a diagnosis or treatment, or knowing there is no underlying medical issue
(ii)	**Any possible benefits to the carer or comforter**	▪ Knowledge that a family member, partner, friend or dependant is receiving medical attention and will be able to have the examination, 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?

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 exposure and can take different forms including verbal discussions, posters, information leaflets or appointment letters. Further detail is provided in Chapter 14 (Communicating benefits and risks). 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, such as pregnancy status, name and relationship to the individual exposed.

The employer must establish dose constraints for carers and comforters [Regulation 6(5)(d)(ii)]. 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. Different dose constraints can be set for each modality. The advice of the MPE should be sought when setting appropriate dose constraints.

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 ALARP within the dose constraint. This may include appropriate use of personal protective equipment (PPE), advice on positioning within the room and guidance to be given to the carer and comforter, including 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 identification against.

Table 16.4 summarises the requirements for carers and comforters and associated matters to consider.

Table 16.4: Regulatory requirement 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
Entitlement **Schedule 2 (b)**	▪ Identifying appropriate individuals entitled to act as practitioner for justification of exposure to carers and comforters
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
Communicating benefits and risks **Schedule 2(i)**	▪ Information leaflets and posters 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 ▪ Involvement of the MPE

17. Health screening and individual health assessment

The investigation of asymptomatic individuals falls into two distinct categories, and IR(ME)R applies to both:

- Health screening [Regulation 3(b)]
- Individual health assessments (IHAs) [Regulation 3(e)].

Those invited to participate in health screening programmes are asymptomatic (having no clinical signs or symptoms of a disease) but are part of an apparently healthy target group or populations who are deemed to be at increased risk from a specific condition or disease.

IHAs are used for those asymptomatic individuals who, based on their own personal circumstances, may wish to seek reassurance by excluding unknown underlying disease. In general, IHAs are not provided by NHS services.

National screening programmes

The UK National Screening Committee (UK NSC) advises ministers in the four UK countries about national screening programmes. Their remit is to assess the evidence and decide if the implementation of a national screening programme will result in more benefit than harm at a societal and individual level. They do this by using strictly defined criteria and review processes.[88]

National screening programmes are proactive, evidence-based, planned, resourced and nationally co-ordinated. National screening programmes select participants from a local population who may be considered to be at risk of a particular condition or disease. Those selected receive an invitation to attend for a diagnostic test rather than seeking a referral from their doctor.

National screening programmes provide clearly defined care pathways, which include further investigation and treatment when required. An example of a national screening programme involving exposures to ionising radiation is the NHS Breast Screening Programme (NHSBSP).[38]

National screening programmes must follow all the requirements for IR(ME)R, including justification, optimisation and training. There are some specific requirements for health screening programmes and these are listed in Table 17.1.

Table 17.1: Requirements for health screening programmes

Regulation	Things to consider
Justification for health screening programmes must consider recommendations or guidelines from 'medical scientific societies or relevant bodies' **Regulations 11(3)(a) and 11(3)(c)**	▪ UK NSC recommendations ▪ Clear justification process described in employer's procedure
Practitioner and operator must pay attention to optimisation for health screening programmes **Regulation 12(8)(b)**	▪ National QA programmes are set and must be adhered to ▪ Establish specific screening protocols

A 52-year-old woman receives an invitation to attend the NHS Breast Screening Programme for a mammogram. The woman is provided with an information leaflet relating to the benefits and risks of the exposure prior to the appointment.[89]

During the identification and information process the operator discovers the patient has breast implants. The local authorisation guidelines include criteria that individuals with breast implants require additional views. The radiographer on the mobile unit is not trained to perform these additional views. This is explained to the individual and another appointment is arranged at the breast screening centre for the following week.

In this scenario, it was not possible for the operator (radiographer) to authorise and perform the exposure on the individual. It is possible to screen women with implants on a mobile unit, but on this occasion the operator was not trained to carry out these additional views. Imaging of women with breast implants should only be undertaken by a trained and entitled registered radiographer.[90]

Individual health assessment (IHA)

IHAs are directed at individuals rather than groups or populations. An IHA is defined as any investigation involving exposure to ionising radiation on an asymptomatic individual wishing to exclude any unknown underlying health issues.

In its 12th report, COMARE stated that services providing whole-body CT scanning of asymptomatic individuals should stop doing so immediately.[40] It went on to provide recommendations that should be followed for CT scanning of asymptomatic individuals for specified areas/conditions.

Any exposure made as part of an IHA must follow all the requirements for IR(ME)R, including compliance with the employer's procedures for referral, justification, optimisation and evaluation, in the same way as any other medical or non-medical exposures.

A 45-year-old man is concerned that he may develop dementia as his brother has recently been diagnosed with early onset dementia. He has no symptoms but is keen to take preventative measures and wants to be sure there are no signs of the disease in his brain. He enquires with an independent healthcare provider about the possibility of a CT scan of his head for reassurance. He is asked to complete a comprehensive health questionnaire, which is reviewed by a consultant neuroradiologist entitled as a referrer and practitioner for this healthcare provider. The practitioner assesses the benefit to this individual of identifying early structural signs of dementia against the risk of the ionising radiation and recommends an MRI scan is done instead.

A 60-year-old male smoker who has no symptoms, but does have a strong family history of coronary artery disease, wishes to check his health status. He carries out an online search and finds a company offering coronary health assessments. The individual organises an appointment and meets with a consultant cardiologist.

An extensive health questionnaire is completed and reviewed. The cardiologist who is entitled as a referrer and practitioner for this company completes a referral for a calcium-scoring CT scan. The same cardiologist also justifies the exposure after weighing up the benefits and risk associated with the exposure. This information is shared with the individual and the scan is scheduled for later that same day.

In the IHA scenarios described, the practitioner must consider all the requirements of Regulation 11(2). This will include the characteristics of the individual, such as age, gender and clinical history, the benefits and risks to the individual from an exposure and any available alternative techniques that do not involve ionising radiation.

Justification of exposures for asymptomatic individuals

Justification of an exposure for an IHA may consider risk factors rather than symptoms. Regulation 11(3)(c) states that the practitioner must justify the exposure as having shown sufficient net benefit and must have regard in particular to any guidelines issued by appropriate medical scientific societies, relevant bodies or the Secretary of State. This applies to all asymptomatic individuals, including exposures for IHAs.[6]

Health screening programmes for an identified healthy population at increased risk of a specific disease and individual health screening of asymptomatic individuals require exposures to be justified and optimised in the same way as for other medical and non-medical exposures. Health screening programmes are likely to come under the governance of the NHS and have strict compliance criteria.

18. Non-medical imaging exposures (using medical radiological equipment)

Non-medical imaging (NMI) exposures are defined as exposures that do not give a direct health benefit to the individual undergoing the exposure. IR(ME)R applies to NMI exposures performed using medical radiological equipment designed and installed with the intention of being used for medical diagnosis, treatment or screening of individuals.

Examples of NMI using medical radiological equipment are:

- Assessment for employment purposes (occupational health checks)
- Assessment for immigration/emigration purposes (visa application process)
- Assessment for insurance purposes (medico-legal claims)
- Assessment of radiological age (bone age hand X-rays)
- Identification of concealed objects within the body (drug smuggling).

NMI exposures that use non-medical equipment, such as security screening at airports and ports, are not covered by IR(ME)R. IR(ME)R does not apply to security screening within prisons where this is carried out using non-medical equipment. However, IR(ME)R does apply to any security screening using medical radiological equipment.

Where NMI exposures are performed, there must be an employer's procedure [Schedule 2(m)] describing the process to be followed by the duty holders involved with these exposures. If NMI exposures are not performed by the organisation, the employer's procedure should clearly state this.

NMI exposures using medical radiological equipment must follow the IR(ME)R framework, requiring referral by a registered healthcare professional, justification and authorisation. Exposures need to be optimised taking into account the specific objectives of the examination, such as a reduction in the number of views required. The availability of previous imaging should be considered as part of the justification process.

Regulation 6(5)(c)(iii) says that the employer, where it is practicable (there are enough of these examinations performed) must establish LDRLs for standard NMI exposures.

Regulation 6(4) requires the employer to ensure that written protocols are in place for every type of standard NMI exposure carried out by the organisation. Consideration should also be given to including a description of how NMI exposures may be identified by the operator (for example, using a specific code on the RIS).

Table 18.1 provides some examples of practices involving NMI exposures, but this list is not exhaustive.

Table18.1: Examples of non-medical imaging exposures

Non-medical imaging exposures	Examples
Employment Examinations may form part of pre-employment medical assessments or planned review to evaluate and monitor individuals[91,92]	▪ Commercial pilots and air crew ▪ Divers ▪ Miners ▪ Oil rig workers ▪ Heavy goods vehicle (HGV) drivers
Immigration/emigration Many countries require individuals to undergo chest radiography as part of the visa application process	▪ TB screening
Insurance Previously known as medico-legal exposures	▪ Cervical spine X-ray for whiplash injury
Radiological assessment for age Used in specific circumstances to determine the age of an individual who may be lacking legal documentation When justifying the examination, the practitioner should consider the possibility that the individual may be a child	▪ Individuals seeking asylum in the UK
Identification of concealed objects within the body The individual may not have any clinical symptoms and the purpose of the examination is to identify internally concealed drugs or objects	▪ Individuals entering the UK ▪ Individuals in prison or custody

A solicitor sends a letter to the imaging department requesting a cervical spine X-ray on a patient who is putting in a claim for whiplash injury following a car crash. The letter is reviewed by a radiologist, who then arranges for the appropriate examination to be undertaken. A referral is provided by the radiologist (as the referrer), who also justifies and authorises the examination (as the practitioner). The operator performs the X-ray in accordance with the written standard protocol for this NMI examination.

In this scenario, while it is the solicitor who has requested the exposure, they cannot be the referrer under IR(ME)R as they are not a registered healthcare professional. The radiologist who receives the letter completes a referral for the appropriate examination and will, therefore, be the referrer and practitioner justifying the exposure.

A request for a CT scan of the abdomen and pelvis arrives in the radiology department. It is initiated by a Border Force officer and is for an individual suspected of swallowing packages containing drugs. The request is directed to a radiologist, who checks the information complies with an agreed protocol, provides a referral and acts as referrer and practitioner for this examination. The radiologist justifies and authorises the examination and specifies the most appropriate scanning protocol to optimise the individual's radiation exposure.

In this scenario, if the individual was suffering symptoms that could be related to the possible concealment of drugs within the body, this exposure would be for medical purposes and not classed as a non-medical exposure. IR(ME)R applies to both types of exposures.

19. The role of the medical physics expert (MPE)

An MPE has the knowledge, experience and training to provide advice on matters relating to the physics of radiation exposures to patients and other individuals (such as carers and comforters or asymptomatic individuals). While the role of the MPE has existed for many years, IR(ME)R formalises the requirements for MPE recognition, clarifies the role of the MPE and requires the employer to appoint suitable MPEs to cover the type of work being carried out. MPEs should be entitled as an operator in accordance with the employer's procedure.

MPEs are required to gain certification through a designated system; further details on this process can be found on the RPA2000 website.[19]

Regulations 14(2) and 14(3) describe the role of the MPE and their required level of involvement in service provision. Table 19.1 shows the different levels of MPE involvement, which are determined by the hazard and risk associated with each type of practice. There is guidance available for the employer to establish the required whole-time equivalent staffing level for MPEs based on the services being provided.[93]

Table 19.1: Level of MPE involvement in each type of practice

		Level of involvement		
		Closely involved	Involved	Involved as appropriate
Type of practice	Radiotherapeutic practices	■		
	Standardised therapeutic nuclear medicine (NM) practices		■	
	Diagnostic NM practices		■	
	High-dose interventional radiology and CT		■	
	All other radiological practices			■

The availability and proximity of the MPE should bear direct relation to the radiation risk involved with the service provision. For example, an MPE for a non-standard nuclear medicine therapy service should be readily available and normally employed at the site. An MPE for a service providing only low-dose exposures (for example, general radiography in a community hospital or low-dose nuclear medicine exposures in a research lab) could be offsite. The MPE should have a greater level of involvement in high-dose diagnostic radiology, such as interventional radiology, cardiology and high-dose CT. Arrangements should be established and be well communicated between the MPE and staff in the

department, so that advice can be provided in a timely manner where necessary. These arrangements should consider situations such as:

- High-dose examinations on individuals requiring special consideration prior to the exposure (for example, pregnant individuals)
- Investigation and dose assessment following high-dose procedures (for example, skin dose calculations following long and complex interventional or cardiac procedures)
- When a fault is suspected with the equipment.

The MPE should be satisfied with the local control arrangements for the sites where they are entitled.[94] Staff need to be aware of how and when to contact their MPE. The MPE has a wide remit, which can be broadly categorised as shown in Table 19.2. It should be noted that the examples provided in this table are not exhaustive and that the role of the MPE will vary depending on local requirements. Service agreements should clearly describe the responsibilities of the MPE to ensure that all aspects of work are covered, and that work is not duplicated.

Table 19.2: Examples of the roles of an MPE

Area	Role examples
Equipment procurement and commissioning	▪ Preparation of technical specifications and installation design ▪ Advice and input on equipment selection
Equipment management	▪ Acceptance testing ▪ Definition and performance of QA ▪ Provision of advice following QA ▪ Undertaking in-depth QA
Optimisation	▪ Protocol development ▪ Introduction of new and developing techniques ▪ Use of technological features and reconstruction or image presentation
Dosimetry	▪ Dose audits ▪ Establishment of LDRLs ▪ Radiation incident analysis including dosimetry calculations
Regulatory compliance	▪ Input to employer's procedures and policies ▪ Compliance audits

Area	Role examples
Training	▪ Local user QA ▪ Radiation protection training for new staff ▪ Update training for existing staff

The MPE should have knowledge and competence in all the above aspects of the role relating to their own area of practice. The MPE must work collaboratively with IR(ME)R duty holders, for example to ensure that exposures are optimised and image quality is adequate to answer the clinical question.

There may be occasions when further advice from different experts is required to ensure comprehensive radiation protection [Regulation 14(4)]. For example, a radiation protection adviser (RPA) will advise on room design for a new installation and may perform a critical examination on newly installed equipment. The MPE would also be able to offer advice about features of the new equipment and perform commissioning and acceptance tests.

In nuclear medicine, the roles of MPE, RPA and radioactive waste adviser (RWA) are required. For example, for the introduction of a sentinel node service in a theatre where gamma probe QC is required, local rules need to be written and waste protocols developed for theatres.

20. Equipment and quality assurance (QA)

Regulatory requirements for medical radiological equipment were previously divided between the Ionising Radiations Regulations 1999 and IR(ME)R 2000.[5,95] The equipment requirements in IRR2017 were revoked when IR(ME)R 2017 and IR(ME)R(NI) 2018 came into force.

Regulation 15 in 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 in IR(ME)R sets out additional requirements for all equipment installed after 6 February 2018.

Equipment and the employer's responsibilities

IR(ME)R details the duties of the employer in relation to any equipment that delivers ionising radiation to an individual undergoing an exposure, as well as any ancillary devices that can directly control or influence the exposure. This ancillary equipment may include, for example:

- CT contrast injector pump
- Equipment used for gated examinations (for example, cardiac ECG leads)
- Gamma cameras
- Gamma probes
- Radionuclide dose calibrators.

Equipment used for clinical evaluation (for example, reporting monitors) is not included as ancillary equipment but should be included in the QA programme to ensure consistency of set-up and image quality. Table 20.1 describes the employer's duties in relation to equipment.

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 components of a QA programme and refers to operations carried out to improve equipment quality such as testing, monitoring, evaluation and maintenance of equipment.

Table 20.1: Employer's duties regarding equipment

Regulation 15	Things to consider
Implement and maintain an equipment QA programme **Regulation 15(1)**	Arrangements for equipment QA including: ▪ Types of tests ▪ Frequency ▪ Who is responsible for carrying out test handover arrangements? ▪ MPE involvement
Keep an up-to-date inventory of equipment **Regulation 15(2)**	▪ Include all ancillary equipment that can directly influence the exposure ▪ Remove equipment no longer in use

Regulation 15	Things to consider
Carry out testing of equipment prior to use for any medical purpose **Regulation 15(3)(a)**	▪ Programme for acceptance testing
Carry out regular performance testing **Regulation 15(3)(b)**	▪ Agreed programme for local routine QC ▪ Monthly, quarterly or annual medical physics testing
Carry out testing following any maintenance that may affect the equipment's performance **Regulation 15(3)(c)**	▪ Procedure for informing of and co-ordinating testing with medical physics team ▪ Handover arrangements
Specify acceptable equipment performance criteria, ensure measures are in place to improve inadequate or defective equipment performance, and specify corrective action to be taken in the case of defective equipment **Regulations 15(6)(a), 15(6)(b) and 15(6)(c)**	▪ Record QC results ▪ Define action levels ▪ Procedure to take equipment out of service ▪ MPE involvement ▪ Risk register ▪ Image optimisation team
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 fluoroscopy equipment
Equipment must be capable of providing an indication of radiation dose delivered to the patient during any procedure **Regulation 15(5)**	▪ MPE involvement in specification for interventional radiology and CT equipment

Regulation 16 includes the following additional requirements for equipment installed on or after 6 February 2018:

- All equipment that produces ionising radiation must be able to inform the practitioner of parameters required for assessment of patient dose, such as an indication of DAP or DLP [Regulation 16(6)(a)]. Where appropriate, such equipment must have the capability to transfer this information to the person's exposure record [Regulation 16(6)(b)].
- All interventional radiology equipment must have a means of informing those performing the examination, post exposure, of the amount of radiation produced during that exposure [Regulation 16(3)].

- All interventional radiology and CT equipment must be able to transfer dose information to a person's exposure record [Regulation 16(5)].

A multidisciplinary team approach to equipment management is essential. Table 20.2 describes things to consider throughout the life cycle of medical radiological equipment.

Table 20.2: Matters to consider throughout the equipment life cycle

Stage in the equipment life cycle	Things to consider
Selection of equipment	▪ MPE involvement ▪ Procurement phase of equipment selection ▪ Assessment of dose optimisation features on tendered equipment ▪ Choice of the most appropriate equipment to meet the service requirements
Critical examinations	▪ After initial installation ▪ After major service or maintenance where there may be radiation protection implications (eg, replacement X-ray tube or automatic exposure controls (AECs))
Acceptance testing and baseline performance testing	▪ Testing of equipment before clinical use [Regulation 15(3)(a)]
Commissioning	▪ Testing equipment before it is first used ▪ Setting up protocols and optimisation of doses ▪ Working with application specialists, clinical leads and other relevant staff

Stage in the equipment life cycle	Things to consider
QA programme	▪ Testing equipment performance at specified intervals and after major maintenance ▪ Extent of the QA programme depending on the nature and range of equipment in use ▪ Definition of acceptable performance criteria [Regulation 15(6)(b)] ▪ Reporting processes (eg, equipment faults, incidents)
Maintenance	▪ Performance testing on a regular basis [Regulation 15(3)(b)] ▪ Employer's procedures for accepting equipment back into clinical use following service or maintenance [Regulation 15(3)(c)]
Inadequate or defective equipment	▪ Assessment of aging equipment resulting in the doses from medical exposures being significantly greater than local or national DRLs or degradation of image quality ▪ Escalation process for dealing with inadequate or defective equipment [Regulations 15(6)(a) and (c)]

Equipment QA programme

Regulation 15(1)(a) and Schedule 2(d) require the employer to have employer's procedures in place to ensure that equipment QA is implemented and maintained. Regulation 14(3)(b) states that an MPE must contribute to defining the equipment QA programme. How this is achieved will depend on the type of equipment and local agreements regarding who will be responsible for specific tests.[96] The advice of an MPE should be sought when reviewing results of such QC testing that are out of tolerance. More detail can be found on the involvement of the MPE in QA programmes in Chapter 19 (The role of the medical physics expert).

Information and guidance on ionising radiation equipment QA and QC testing can be found in the report series published by IPEM.[97]

The operator has a specific responsibility to consider QA and QC when ensuring that exposures are ALARP [Regulation 12(3)(a)]. Table 20.3 provides examples of what should be considered for inclusion in an equipment QA programme.

Table 20.3: Examples for inclusion in an equipment QA programme

QA programme	Things to consider
When to test	▪ Frequency of standard testing (eg, annually, monthly) ▪ Following an engineer's visit (unless no impact on dose or image quality) ▪ Following fitting of a new part
Who will test?	▪ Radiographer or clinical technologist (eg, daily or monthly tests, post engineer visit) ▪ Medical physics
Prior to external testing (eg, faults, servicing)	▪ Equipment handover (eg, the Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (AXREM) form[98]) ▪ Examine equipment log for known issues and previous engineers' reports
During testing	▪ Specific tests for each equipment type ▪ How to set up specific tests, including distances, exposure parameters and position of phantoms ▪ Record results ▪ Ensure tolerances available ▪ Record of assessment of results against tolerances
After testing	▪ Report any issues verbally and/or in writing to appropriate person (eg, MPE, lead radiographer, QA lead) ▪ Detail actions required (eg, seek MPE advice, repeat test, remove equipment from service) ▪ Record any actions taken and return to service ▪ Equipment handover (eg, AXREM form)
Review and improvement	▪ Review results to demonstrate performance over time ▪ Record of faults and corrective actions ▪ Training records of those performing QC

Equipment inventory

The employer must keep an up-to-date inventory of all medical radiological equipment, including ancillary devices, that can directly control or influence the exposure [Regulation 15(1)(b)] at each site. This inventory must be readily available on request by the enforcing authority and must include [Regulation 15(2)]:

- Name of manufacturer
- Equipment model number
- Serial number or another unique identifier
- Year of manufacture
- Year of installation.

This information is often stored electronically (for example, by the medical equipment management department if there is one). 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 or is decommissioned. Consideration could be given to making some of this information (for example, age of equipment) available to the public upon request.

21. Accidental or unintended exposures

The use of consistent terminology when discussing radiation errors and incidents is essential to assist reporting and analysis.[99,100] Within this chapter, the following terms are used:

- **Event:** Something that happens to or involves a patient or individual.
- **Error:** A failure to carry out a planned action as intended or an application of an incorrect plan. Not all errors lead to radiation incidents (for example, where the error is detected before the individual is exposed).
- **Radiation incident:** An error where the delivery of radiation is different to that intended and which could result in unnecessary harm to the patient.
- **Near miss:** A potential radiation incident that was detected and prevented at any point before an exposure takes place.

Errors, radiation incidents and near misses should be locally reported through incident management systems (for example, Datix, Ulysses). Significant radiation incidents that meet criteria established by the IR(ME)R enforcing authorities must be notified to the relevant enforcing authority.

Accidental or unintended exposures

IR(ME)R defines the terms accidental exposure and unintended exposure in Regulation 2. The Regulations require the employer to provide a system for analysis, recording and reporting of accidental or unintended exposures [Regulation 8(3)]. The regulations differentiate between significant accidental or unintended exposures (SAUE) and clinically significant accidental or unintended exposures (CSAUE). Regulation 8(1) requires the referrer, practitioner and individual exposed or their representative to be informed of a CSAUE. Exposures that are CSAUE and those that are SAUE must be notified to the relevant enforcing authorities. IR(ME)R applies to radiation incidents that involve either equipment or procedural failures.

Significant accidental or unintended exposures (SAUE)

These exposures are significantly greater than intended. The relevant enforcing authorities have published joint guidance on notification thresholds and requirements for SAUE.[67] The regulations require that SAUEs are notified to the relevant enforcing authorities.

Clinically significant accidental or unintended exposures (CSAUE)

The Department of Health and Social Care (DHSC) guidance to IR(ME)R does not define CSAUE and the DHSC has asked the clinical and medical professional bodies to provide further guidance on this topic.[6]The following guidance aims to fulfil this request.

The requirements of IR(ME)R are consistent with the duty of candour and the need to conduct clinical practice in an open and transparent manner.[101] The definition of moderate harm required to trigger the duty of candour has been used as the basis for the following guidance.[102] For stochastic effects, a pragmatic definition in terms of the probability of radiation-induced cancer has been employed as it is not possible to directly align these effects with a definition given in terms of severity of harm.

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.*[103]

It is important to note that justified exposures, where it is known in advance (or becomes apparent during an exposure) that an adverse outcome may occur, are not CSAUE under IR(ME)R. An example is an interventional procedure where the practitioner continues to expose the patient past the dose threshold (alarm) recognising that skin erythema will occur but who makes the clinical decision that continuing with the procedure is in the best interests of the patient. In making this decision, the practitioner must weigh up the dynamic risk of potential skin erythema against the clinical risk of stopping the procedure.

An example of a radiology-related moderate harm incident from the NRLS is that of a broken foot not detected on X-ray, resulting in the patient being sent for extensive physiotherapy with a consequence of further pain and damage.[103] This example would trigger a requirement under duty of candour, but, as there is no increased dose and the exposure was delivered as intended, this is not a CSAUE under IR(ME)R.

Stochastic effects

A CSAUE is defined as an accidental or unintended exposure to ionising radiation that results in a 0.1% (1 in 1,000) or greater lifetime radiation-induced cancer risk. This is consistent with the Chief Medical Officer's report of 1995,[104] which introduced risk classification levels and defined 'moderate risk' as a lifetime probability of death or adverse response of 1 in 1,000. The risk calculation should only assess the risk from the additional accidental or unintended exposure.

For fetal exposures where the pregnancy was not known about, a 0.1% (1 in 1,000) or greater risk of radiation-induced childhood cancer is considered a CSAUE. This is consistent with the threshold for the highest childhood cancer risk group defined in previous advice on radiation protection of pregnant patients.[66]

The MPE must contribute to incident analysis [Regulation 14(3)(f)]. Dose and risk estimates for potential CSAUEs should be calculated by an MPE using age- and sex-appropriate cancer risk factors.[66,105] Consideration should be given to the lowering of lifetime radiation-induced cancer risk associated with subjects with a reduced life expectancy, such as a patient on a palliative care pathway. The MPE assessment of stochastic risks may result in an incident being classified as a CSAUE despite the thresholds for SAUE under Regulation 8(4) of IR(ME)R *not* being met. At the time of producing this document, the SAUE guidance requires all CSAUEs to be notified to the relevant authority.[67]

Deterministic tissue injuries

A CSAUE is defined as an unjustified exposure to ionising radiation greater than:

- 0.5Gy to the lens of the eye[106]
- 0.5Gy to the heart or brain[106]
- 5Gy dose to skin including backscatter for skin reactions (for example, erythema for more than two weeks, more severe skin reactions and permanent partial epilation);[107] extravasation of some radiopharmaceuticals with long half-lives, such as ^{201}Tl or ^{131}I, may result in skin doses greater than 5Gy; this is particularly relevant for therapeutic administrations of radiopharmaceuticals
- 50mGy to the thyroid following the administration of a radiopharmaceutical where there has been a failure in the thyroid blocking procedure.

Psychological harm

The definition of 'harm' in the NRLS guide to good practice includes physical and psychological harm.[103] It is important to recognise that individuals may react differently to being informed about an accidental or unintended exposure. This can be influenced by many factors including:

- The magnitude of the exposure
- The age of the individual
- The mental health of the individual
- Whether the individual is pregnant or trying to conceive
- The information provided following an analysis of the accidental or unintended exposure (what they are told)
- How the news of the accidental or unintended exposure is delivered (how they are told).

In rare circumstances, an accidental or unintended exposure may be a CSAUE if it affects the individual's quality of life to a level that requires intervention or treatment.

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 CSAUE has occurred and provide information on the outcome of the investigation of the incident.

Good practice will include the requirements of Schedule 2(l) within a comprehensive radiation incident and near miss reporting procedure. Table 21.1 includes things to consider for inclusion in a comprehensive employer's procedure.

Table 21.1: Employer's procedure for local incident reporting, investigation and external notification

Area	Things to consider
Preliminary investigation process	▪ How and when duty holders identify, record and report events ▪ 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 those responsible for managing the internal escalation process (eg, the radiation protection supervisor (RPS) or senior site lead)
	▪ Involvement of the MPE (eg, estimation of overexposure) ▪ External notification thresholds and timescales (eg, SAUE Guidance,[67] CSAUE definition) ▪ Identify responsible person for notifying the relevant enforcing authority (where required)
Detailed investigation process	▪ Identify root causes and contributory factors ▪ Remedial action to prevent or minimise similar recurrence ▪ Provide exposure factors to estimate doses involved, to allow the MPE to calculate the risk to the individual(s) exposed ▪ Establish if any other individuals may be similarly affected ▪ Trend analysis and comparison with other similar errors ▪ Systems analysis and effectiveness of current safety barriers ▪ Report on what actually happened and compare with what should have happened

Area	Things to consider
Clinically significant accidental or unintended exposures (CSAUE)	▪ Estimation of dose delivered and risk to individual exposed ▪ Involvement of the MPE ▪ Informing the individual exposed or their representative, the referrer and practitioner
Informing the individual exposed/ representative, referrer and practitioner	▪ Identify the person responsible for informing the individual exposed or their representative ▪ 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 incidents or errors[108] ▪ Systematic analysis of incidents or errors, as part of a no-blame safety culture ▪ Lessons learned, including identifying areas that require review and improvement and informing of changes to practice ▪ Communicate and share learning themes to all stakeholders within the organisation

When individuals are informed of errors and an explanation of the risks is given, it is advisable to consider risks in broad categories.[102,105] 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 (Communicating benefits and risks).

It is considered good practice for all near misses and errors to follow the same process, so any lessons learned can be applied and may prevent an error from occurring. The process of investigation should be standardised.

Regulation 8(4) sets out the process the employer must follow when it is believed 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[67]
- 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.[67] 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, the Scottish Ministers delegate the powers to inspect compliance with IR(ME)R to Healthcare Improvement Scotland (HIS)
- In Wales, the 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.

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 improved.[109]

System 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 near misses and errors.

Most errors or near misses are not just a series of random unconnected events. They may be linked to poor systems, processes or culture. They often have common root causes, which when recognised 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 events are not reported and analysed. Guidance for coding and classification of errors and near misses is available.[108]

Documentation relating to errors and near misses should be retained in line with relevant guidance.[110] Clinical departments should keep records of errors and near misses. These should be made available to all staff to facilitate learning and support safer working.

Safety culture

Safety in healthcare is recognised as being about maximising the things that go right for patients and minimising the things that go wrong. A systems approach to safety considers multiple factors rather than apportioning individual blame.[111]

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 learned 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 21.2 provides examples for consideration of areas to include in this employer's procedure.

Table 21.2: Employer's procedure to reduce the probability and magnitude of accidental or unintended exposures

Area	Things to consider
Optimisation	▪ Modality-specific training ▪ Use of DRLs ▪ Peer review of images to assess image quality, positioning, collimation, and so on ▪ Image optimisation teams (IOT) ▪ MPE involvement
Communication	▪ Effective communication with the patient to facilitate compliance during the examination ▪ Communication with all duty holders to share learning themes and promote compliance with the employer's procedures ▪ Communication with safety and governance committees
Audit	▪ Audit of appropriateness of referrals and justification ▪ Audit of adherence to ID process ▪ Monitoring of compliance with employer's procedures
QA programmes	▪ Robust QA programme for documentation and equipment ▪ Procedures and protocols are documented, regularly reviewed and monitored through a robust programme of internal and external audit
Training programmes	▪ Training for all duty holders, with supporting evidence of competence once training is complete, and ongoing CPD
Error and near miss analysis	▪ Analysis of trends to identify any need for change in practice or procedure or a need for further training ▪ Shared learning internally or across a trust or health board

22. 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 the ARSAC and issued by the appropriate licensing authority.[94] Regulation 2 defines what the appropriate licensing authority is for employers and practitioners in England, Scotland, Wales and Northern Ireland. These are listed in Table 22.1.

Table 22.1: Licensing authorities in the UK

	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 site where radiopharmaceuticals are 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 this may be considered as part of 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.

A practitioner holds a licence for the full range of diagnostic nuclear medicine procedure codes listed in the ARSAC Notes for Guidance. The licensed practitioner is entitled by an employer at two hospital sites of a trust/health board, one of which has a PET-CT scanner. At the site with the PET-CT scanner, 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 non-PET procedure codes listed on their licence.

Detailed guidance on how to apply for a licence is provided by ARSAC.[21]

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 23 (Research).

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.[21]

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

Regulation 240 of the Human Medicines Regulations 2012 allows IR(ME)R operators to administer other medicines as part of a nuclear medicine procedure, such as diuretics as part of a renogram or iodinated contrast as part of a PET-CT study.[112] 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.

23. Research

IR(ME)R contains a number of research-specific requirements that must be met in addition to those that apply to all medical and non-medical exposures. Table 23.1 lists examples of the requirements and things to consider when carrying out research examinations.

Table 23.1: Additional requirements for research exposures

Regulations	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 **Regulation 11(1)(d)**	▪ All research trials must be approved by a recognised research ethics committee (REC) before commencing ▪ All research trials involving the administration of radioactive substances must be approved by the 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 23.2 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 23.2: Considerations for inclusion in employer's procedure on research

Requirement	Things to consider
Approval by a recognised REC and ARSAC (administration of radioactive substances)	▪ Brief description of how the local research and development approval process ensures that REC and, where applicable, ARSAC approvals are in place
Practitioner and employer licences	▪ Process to ensure that appropriate licences are held to cover all administrations of radioactive substances required by the research trial

Requirement	Things to consider
Individuals participate voluntarily	▪ Clear description of the research consent process ▪ The process for individuals who are unable to consent (eg, paediatric patients)
Individuals informed in advance about the risks of the exposure	▪ Participant information sheet (PIS) ▪ Radiation risk information within the PIS should follow guidance from the Health Research Authority (HRA)[113]
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 in place for research trials where no direct medical benefit is expected (eg, studies on healthy volunteers) ▪ Dose constraints must be established for all research trials involving *standard* radiodiagnostic procedures ▪ Dose targets must be established where direct patient benefit is expected (eg, experimental diagnostic or 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 reasonable variations in local practice (eg, available equipment) taken into consideration
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:[114]

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, as part of either 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 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 typical examples are available from the HRA to help determine whether a research trial includes research exposures.[114]

A study seeks to gain further data on the safety, performance and efficacy of a CE-marked cardiac stent already established as standard treatment at participating centres. Patients have fluoroscopy-guided insertion of the stent as standard clinical practice. The research protocol specifies that the examinations are conducted according to a standard of care at each centre and the data is collected for the purposes of the research, but the research protocol does not specify any conditions on the data (for example, the acquisition parameters).

The exposure in this scenario is *not* a research exposure. The examination is justified and authorised as part of normal clinical care and not for the purpose of the research. Consent to undergo the exposure is not part of the consent to participate in the research trial.

A randomised controlled trial will assess the efficacy of a novel chemotherapy agent in comparison with the standard regime for patients with advanced ovarian cancer. The research protocol requires patients to have CT scans after one month, three months, six months and thereafter six-monthly until disease progression is in line with the standard of care. A radionuclide bone scan will be performed to check for metastatic disease prior to treatment and, if positive, this will be repeated at six-monthly intervals.

In this scenario, the CT scans and bone scans *are* research exposures (even though they would be standard care outside the research trial). They are needed to assess the endpoints of the research and are an integral part of the research protocol. The research protocol gives clear information as to how the exposures should be conducted. It specifies the frequency, administration, method, processing or clinical evaluation of the exposures, including specifications of machinery to be used.

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 research ethics committee (REC). Further detailed guidance is available from the HRA on how to apply for REC approval.[114] 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.[94] 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 regarding the study population, but the individual characteristics of each patient, including contraindications, 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.[94]

Practical considerations

IR(ME)R requires employer's procedures to provide safeguards for medical and biomedical research trials. It is important that radiology and nuclear medicine staff can identify those exposures that are for research purposes. This can be achieved in several ways, such as by selecting a drop-down menu on the RIS or using a specific study code on the referral. These

processes should be described in the employer's procedures. A list of current trials should be made available to staff within radiology and nuclear medicine departments.

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
- The imaging protocol.

It may be helpful to consider having a radiology 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.

The employer's procedure should also describe how referrers must identify research exposures to enable staff to recognise the referral as research. This in turn enables the practitioner and the operator to select the correct protocol for the research study.

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

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

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Appendix 1. Glossary

Term	Definition
Adequate training	Training that satisfies the requirements of IR(ME)R Schedule 3 with theoretical knowledge and practical experience.
Authorisation	Confirmation that the process of justification has occurred. Evidenced either by hand or electronic signatures.
Carer and comforter	Individual knowingly and willingly incurring an exposure to ionising radiation, other than as part of their occupation, by helping in the support and comfort of an individual undergoing or having undergone an exposure.
Clinical audit	A systematic examination or review of medical radiological procedures that seeks to improve the quality and outcome of patient care.
Clinical evaluation	An assessment of an exposure by an appropriately trained and competent operator to evaluate the outcome.
Clinically significant accidental or unintended exposure	An accidental or unintended exposure that has had or is expected to have caused moderate harm to the individual. Effects may be physical or psychological and may require intervention or treatment to the individual exposed.
Continuous professional development	The planned acquisition of knowledge, experience and skills and the development of personal qualities throughout the working life of an individual.
Dose constraint	Part of the optimisation process; a dose constraint is a restriction set on a prospective dose.
Dose target	Target levels of doses planned for research exposures where direct patient benefit is expected (eg, experimental diagnostic practices).

Diagnostic reference level (DRL)	Radiation dose levels, or administered activity, for typical diagnostic examinations on standard size adults and children for broadly defined types of equipment.
Employer	The employer, as a duty holder, is responsible for providing a framework within which professionals undertake their functions. The definition of employer relates to health and safety functions rather than employment matters.
Entitlement	This is the process of verifying that the duty holder has the necessary training and competencies to undertake the task as defined in their scope of practice.
Error	A failure to carry out a planned action as intended or an application of an incorrect plan. Not all errors lead to radiation incidents (for example, when the error is detected before the individual is exposed).
Event	Something that happens to or involves a patient.
Image optimisation team	A multidisciplinary team of experts working to ensure a consistent approach to optimisation across modalities.
Justification	An intellectual process of weighing up the potential benefit of an exposure against the detriment from the radiation dose received by that individual.
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.
Medical physics expert	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 medical exposure whose competence in this respect is recognised by the Secretary of State.
Near miss	A potential radiation incident that was detected and an error prevented at any point before an exposure takes place.

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, any comments apply equally to health boards and independent healthcare providers.
Non-medical imaging	Exposures that do not have a direct health benefit to the individual undergoing the exposure.
Operator	Any person who is trained and entitled to carry out the practical aspects of an exposure.
Optimisation	The process by which individual doses are kept as low as reasonably practicable.
Policy	A high-level statement governing the conduct of activities in an organisation. Policies outline what will be done with minimal detail as to how this will be achieved.
Practitioner	A registered healthcare professional who is entitled to take responsibility for an individual exposure. The primary role of the practitioner is to justify and authorise exposures.
Procedure	A detailed and documented description of the steps that should be taken or the method that should be followed.
Protocol	Written protocols include step-by-step descriptions of how an examination is carried out. They should be evidence-based, reflect current practice and be ratified through the QA process.
Quality assurance	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; quality control is a part of quality assurance.

Quality control	The set of operations (programming, co-ordinating, implementing) intended to maintain or to improve quality, including monitoring, evaluation and maintenance at required levels, of all characteristics of performance of equipment that can be defined, measured and controlled.
Radiation incident	An error where the delivery of radiation is different to that intended and which resulted in unnecessary harm to the patient.
Referrer	A registered healthcare professional who is entitled to refer individuals for exposures involving ionising radiation. In Northern Ireland this also includes medical practitioners registered with the Medical Council of Ireland.
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.
Relevant enforcing authority	Enforcing authorities for IR(ME)R: England, Care Quality Commission Northern Ireland, Regulation and Quality Improvement Authority Scotland, Healthcare Improvement Scotland Wales, Healthcare Inspectorate Wales.
Significant accidental or unintended exposure	An exposure that was significantly greater than that intended. The regulations require that significant accidental or unintended exposures are notified to the relevant enforcing authorities.
Scope of practice	A range of skills and tasks based on professional registration, education, training, knowledge and experience.
Supervision	The action or process of watching and directing what someone does or how something is done and being in a position to change this when required.

Appendix 2. Abbreviations used in this document

Abbreviations	
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
CCT	Certificate of Completion of Specialist Training
COMARE	Committee on Medical Aspects of Radiation in the Environment
CoR	College of Radiographers
CSAUE	Clinically significant accidental or unintended exposure
CT	Computed tomography
CTDI	Computed tomography dose index
DAP	Dose area product
DHSC	Department of Health and Social Care
DLP	Dose length product
EANM	European Association of Nuclear Medicine
FRCR	Fellowship of the Royal College of Radiologists
GMC	General Medical Council
HCPC	Health and Care Professions Council
HRA	Health Research Authority
IHA	Independent health assessment
IPEM	Institute of Physics and Engineering in Medicine
IRAS	Integrated Research Applications System
LDRL	Local diagnostic reference level

LMP	Last menstrual period
MGD	Mean glandular dose
MRI	Magnetic resonance imaging
NDRL	National diagnostic reference level
NICE	National Institute for Health and Care Excellence
NRLS	The National Reporting and Learning System
PACS	Picture Archiving and Communications System
PET-CT	Positron emission tomography/computed tomography
PIS	Participant information sheet
POM	Prescription-only medicines
QA	Quality assurance
QC	Quality control
RCR	Royal College of Radiologists
REC	Research ethics committee
RIS	Radiology information system
RPA/RPS/RWA	Radiation protection adviser/radiation protection supervisor/ radioactive waste adviser
SAUE	Significant accidental or unintended exposure
SCoR	Society and College of Radiographers
SPECT	Single photon emission computed tomography
WHO	World Health Organization

Appendix 3. Key things to consider when writing 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 to the minimum required by IR(ME)R. Further information can be found in the main body of this guidance, and this 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?
▪ When does the ID check happen?
▪ What questions will the operator ask the individual?
▪ What if there is more than one operator involved in the examination?
▪ What is the process if there is a discrepancy with the individual's demographics?
▪ What is the process if verbal communication is not possible, because of, for example, language barriers, age, mental capacity, or being unconscious or sedated?
▪ How is the ID checking process recorded?
▪ How is the correct radiopharmaceutical identified for nuclear medicine?
(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?
▪ Should a training matrix be used?
▪ How often are training, competencies and entitlement reviewed and by whom?
▪ How do staff demonstrate their entitlement and scope of practice?
▪ Who holds the training records?
(c) Enquiries to individuals who may be pregnant or breastfeeding
▪ Who is responsible for checking pregnancy and breastfeeding status? (include staff outside radiology)
▪ What is the age range for pregnancy and breastfeeding enquiries?
▪ When is pregnancy and breastfeeding checking required? (describe any exceptions)
▪ When and where do the pregnancy and breastfeeding checks happen? (include areas outside radiology)
▪ How will responses be recorded?
▪ What are the measures to raise awareness? (eg, posters, appointment letters)
▪ Is there an explanation of when the 10/28-day rule applies?

- What is the process when more than one operator is involved in an exposure?
- Where is information documented?
- What is the process if an individual is unsure of or says that they are pregnant?
- How are protocols optimised for pregnant or breastfeeding individuals?
- Include contact details and safeguarding procedures.
- Include breastfeeding interruption times for common examinations.

(d) Quality assurance programme for written procedures and equipment

Written procedures

- What should be included for a standard template? (eg, version number, author, authorised by, issue date, review date)
- What is 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 is there and how often will it be tested? (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 QC?
- 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 dose (include areas outside of radiology/NM)
- What dose indicators for each modality will be recorded?
- What is the process for setting threshold trigger levels (eg, audible alarms)?

(f) Use and review of diagnostic reference levels

- What DRLs are in place? (eg, local, national, paediatric)
- Where they can be found?
- How often are they reviewed and by whom?
- How will staff know if DRLs are being consistently exceeded?
- What actions are to be taken by staff and the employer if DRLs are consistently exceeded?
- What DRLs are needed for hybrid imaging?

(g) Research

- What is the process for local research and development approval?
- What is the process to ensure appropriate employer and practitioner licences are in place?
- Is there a link to the participant information sheet?
- Is there a description of how dose constraints are set?
- Is there a description of how dose targets are set?
- Is there a description of how adherence to dose constraints is ensured?
- How do duty holders identify research exposures?
- What is contained in the research file and how can duty holders access this?

(h) Written information for nuclear medicine

- How is the advice on precautions to observe after the exposure provided?
- How is the individual informed of the risks from the exposure?
- When is the information provided to the patient/individual?
- Where can additional information be found?

(i) Communication of benefits and risks

- What information will be given to the individual exposed or their representative?
- Who will provide this information?
- How will the information be provided? (eg, verbal, posters, information leaflets)
- Where will the information be provided?
- How will staff access support for additional information if required? (eg, MPE)
- What training is provided for staff on the delivery of this information?
- How will the method and level of communication reflect the risk? (eg, general radiography posters, interventional procedures, verbal and written information given as part of the consent process)
- What is the process where verbal communication is not possible?

(j) Recording of clinical evaluation

- How is clinical evaluation recorded?
- Where is it recorded? (eg, RIS, PACS or in the patient's notes)
- Who records the clinical evaluation? (include areas remote from radiology)
- When should exposure factors be included in the clinical evaluation?
- What happens if clinical evaluation takes place outside the radiology department?
- How is training provided to staff carrying out and recording clinical evaluation? (include those working remotely from radiology)
- How is the operator carrying out this task identified and entitled?
- What is the process in place for unexpected findings?
- How and when are audits carried out to assess compliance with the employer's procedure and discrepancies with clinical findings?

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

Include a list of local measures that are taken to reduce the probability and magnitude of accidental or unintended exposures, such as:

- Adherence to the individual/patient identification process
- Review of employer's procedures to ensure they reflect local practice
- Optimisation process
- MPE involvement
- Establishment and use of DRLs
- Image optimisation team (IOT)
- Equipment QA programme in line with recommended guidance
- Training and competency assessments
- Induction programmes for new staff
- Peer review of images
- Clinical audit
- Investigation and analysis of errors and near misses
- How feedback is shared with staff following incidents

(l) Clinically significant unintended or accidental exposures

- How do duty holders identify and report radiation incidents including near misses?
- What information is required and who communicates the information to the MPE?
- How and where is this information recorded?
- Who investigates?
- Who will inform the referrer, practitioner and individual?
- How will the information be communicated (eg, verbally, written) and where is this communication recorded?

- If the decision is made not to inform the individual or their representative, where is this recorded?
- How are CSAUEs notified to the relevant enforcing authority and who is responsible for the notification?
- How will the outcome of the investigation be shared?
- How will feedback and learning be delivered to staff?

(m) Non-medical imaging (NMI) exposures

- How are NMI referrals identified?
- Who will authorise and justify these referrals?
- How are these exposures optimised? (eg, specific protocols, reduced number of views)
- If NMI is not performed, is this clearly stated in the employer's procedure?

(n) Carers and comforters

- Who will justify and authorise the exposure?
- When may an individual be a designated carer and comforter?
- What information is recorded and where? (eg, relationship to individual, on RIS)
- What information will be provided in relation to benefits and risks?
- How will this information be presented?
- How are pregnancy enquiries carried out and recorded?
- How will the dose be ALARP? (eg, PPE, where to stand, restrict close contact time)
- What are the dose constraints?
- Are there special considerations for those who will not *normally* be a carer or comforter? (eg, pregnant women, children acting in a caring role)
- Are there non-standard situations where additional information is required?

Appendix 4. Example template for a local training record

This is an example of how a training record could be presented. The detail provided is not intended for direct adoption in the clinical environment. Employers should adapt the template to reflect local service provision and practice.

Name of duty holder	
Job title	
Qualification(s) and year obtained	
Training records held by	
Department	
Equipment	

Tasks	Trained by (name and role)	Trainer signature and date	Trainee signature	Date
Switch equipment on, and off location of emergency stop				
Warm-up procedure				
Daily/weekly QC test				
Selecting patient from work list				
Selecting correct protocol				

This record indicates that the above individual has received training, demonstrated satisfactory understanding to the expected standards and can apply the knowledge into practice consistently and competently. Their signature indicates their agreement with the above and confirmation that they have read and understood the associated documentation.

Name and signature of assessor:	Name and signature of trainee:	Date completed:

Appendix 5. Example template for individual scope of practice

This is an example of how an individual scope of practice could be presented. The detail provided is not intended for direct adoption in the clinical environment. Employers should adapt the template to reflect local service provision and practice.

Name of duty holder			
Job title			
Qualification(s) and year obtained			
Registration number		Date checked	
Training records held by			
IR(ME)R employer's procedures read by duty holder	Signature	Date	

Referrer functions	**Competency assessed by (name & role)**	**Signature and date**	**Duty holder signature**	**Date**
Competent to refer for all general radiography examinations				
Competent to refer for nuclear medicine imaging studies				
Competent to refer for non-medical imaging examinations				

Practitioner functions	**Competency assessed by (name and role)**	**Signature and date**	**Duty holder signature**	**Date**
Competent to justify referrals for all X-ray general radiography examinations				
Competent to justify referrals for nuclear medicine imaging procedures as outlined in their practitioner licence				
Competent to justify referrals for mammography				

Operator functions	Competency assessed by (name and role)	Signature and date	Duty holder signature	Date
Competent to carry out patient identification				
Competent to authorise against nuclear medicine guidelines issued by the practitioner				
Competent to clinically evaluate appendicular general radiography examinations for adults				

Additional functions	Competency assessed by (name and role)	Signature and date	Duty holder signature	Date

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 expected standard. The appropriate manager will update the competency matrix until reassessment.

Removed functions	Entitlement removed by (name and role)	Signature and date	Duty holder signature	Date

This record indicates that the above individual has received training, demonstrated satisfactory understanding to the expected standards and can apply the knowledge into practice consistently and competently. Their signature indicates their agreement with the above and confirmation that they have read and understood the associated documentation.

Entitled by (name and role): Signature: Date:

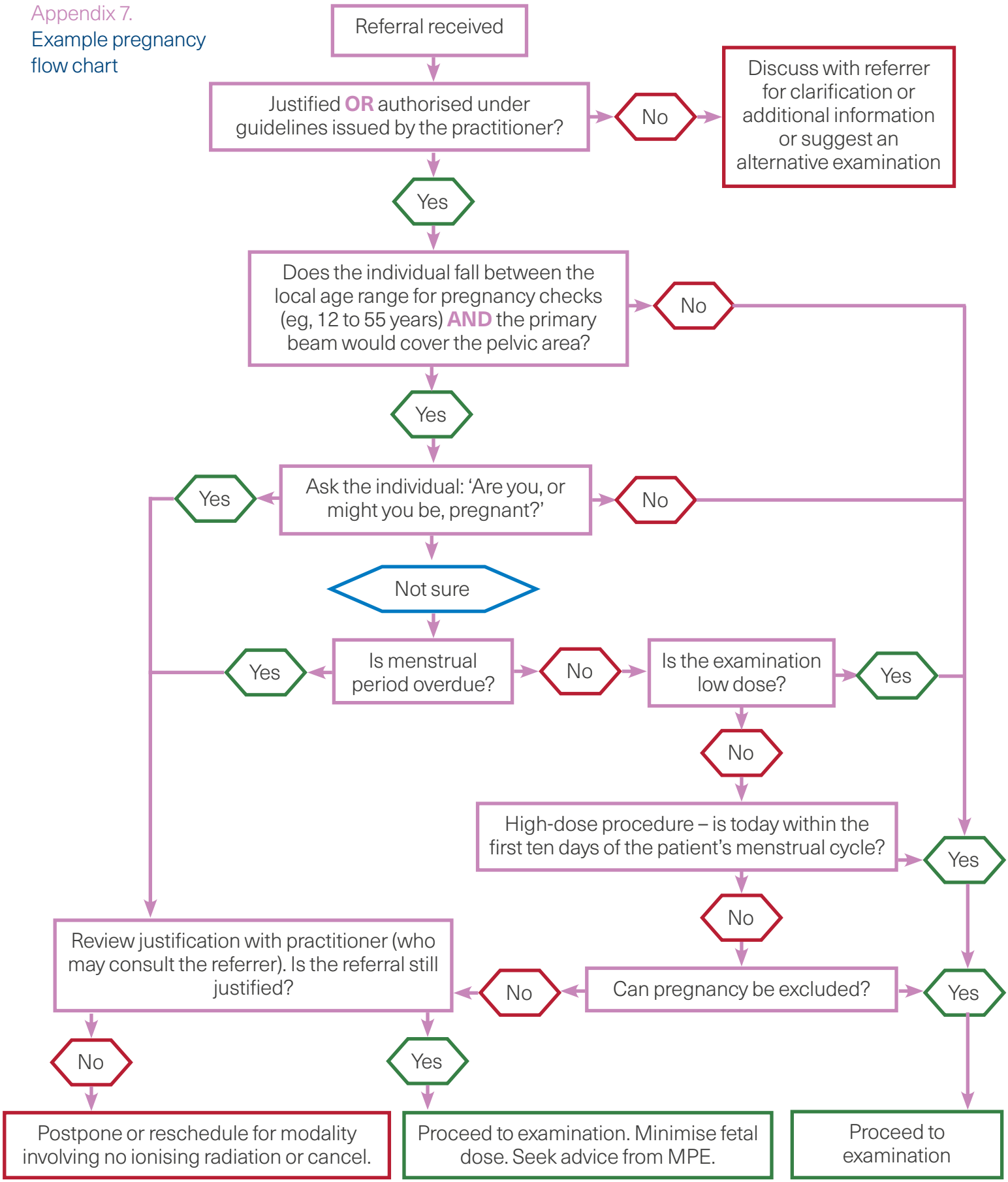
Appendix 6. Group entitlement

Group entitlement may be adopted in situations where a group of duty holders have the same defined scope of practice (for example, GP referrers). Below is an example of how this may be summarised for referrers in the employer's procedures or the radiation safety policy, but this format can be extended to other duty holder roles. Additional detail is required to define the group scope of practice and identify the trained individuals within the group. The detail of examples given is not intended for direct adoption in the clinical environment. Employers should consider how this template could be adapted to their local practice.

Referrers

Staff group	Registration	Example scope of referral	Entitled by
General practitioners	GMC	▪ General radiography examinations only	Clinical director
Radiographers	HCPC	▪ Orbits X-ray; IOFB for MRI ▪ CT chest following positive CTC	Radiology services manager
Emergency nurse practitioners	NMC	▪ Extremity radiography of patients >5 years	Clinical director
Radiologists	GMC	▪ All examinations	Clinical director
Cardiologists	GMC	▪ All cardiac imaging	Clinical director
Specialist oncology nurse practitioners	NMC	▪ NM bone scan	Clinical director

Appendix 7. Example pregnancy flow chart



Appendix 8. Working party membership

Working party membership

- British Institute of Radiology (BIR)
  - Elizabeth Benson
  - Cristiona Logan
- British Society of Paediatric Radiology (BSPR)
  - Dr Jeannette Kraft
- Institute of Physics and Engineering in Medicine (IPEM)
  - Debbie Saunders and members of the DR SIG
  - Debbie Peet and members of the RP SIG
  - Peter O'Sullivan and members of the NM SIG
- Public Health England Medical Exposures Group
  - Louise Fraser
  - Yvonne Sullivan
  - Gail Woodhouse (interim chair)
- The Royal College of Radiologists (RCR)
  - Dr Peter Riley (chair)
  - Dr Richard Graham
  - Dr Stewart Redman
  - Fionnuala Morrissey (secretariat)
- Society and College of Radiographers (SCoR)
  - Lynda Johnson
  - Maria Murray

Clinically significant working party membership

- The Royal College of Radiologists (RCR)
  - Dr Peter Riley (chair)
  - Dr Richard Graham
- Public Health England Medical Exposures Group
  - Louise Fraser (interim chair)
  - Gail Woodhouse (observer)
- British Institute of Radiology (BIR)
  - Dr John Kotre
- Institute of Physics and Engineering in Medicine (IPEM)
  - Matthew Dunn
- Society and College of Radiographers (SCoR)
  - Lynda Johnson

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