Clinical Radiology IR(ME)R:

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

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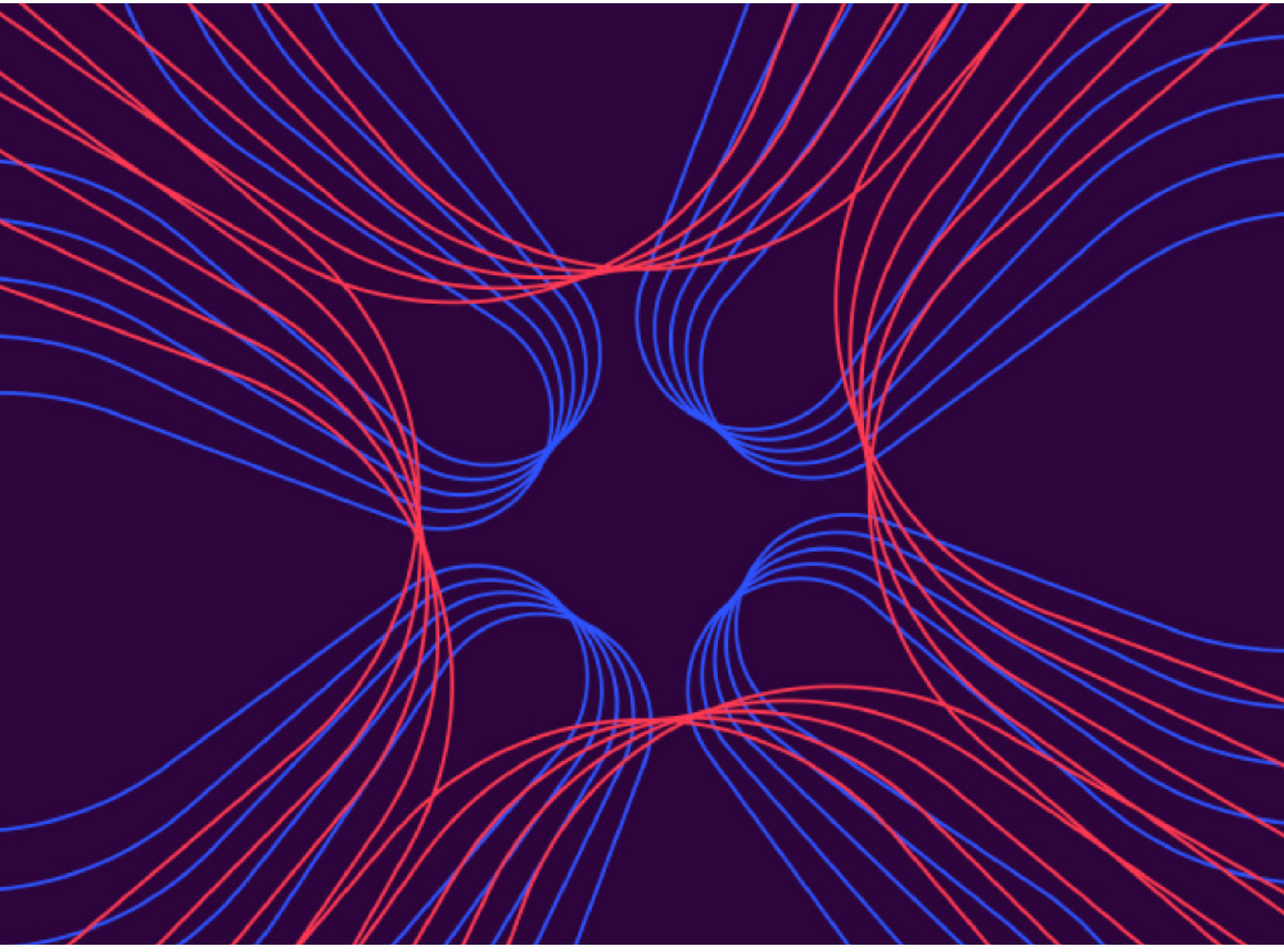
The Royal College of Radiologists



British Institute of Radiology

Institute of Physics and Engineering in Medicine

THE SOCIETY OF RADIOGRAPHERS

UK Health Security Agency

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Foreword

Ionising radiation is increasingly used in medical imaging to support patient diagnosis and treatment. The benefits of using ionising radiation in medical imaging need to be weighed against the risks associated with the detrimental effects of the radiation dose.

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

On 1 October 2024, the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024 came into force in England, Scotland and Wales. The Regulations in Northern Ireland have yet to be amended at the time of publication.

This second edition of guidance seeks to explain how the requirements of the amended Regulations should be interpreted and used in clinical practice. Updates have been made across the document to reflect changes to service provision and developments in technology. Clinical scenarios have been included to enable practical interpretation of the Regulations.

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

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

We hope this document will support the diagnostic and nuclear medicine communities to implement IR(ME)R in their practice.

Dr Stephen Harden
President of The RCR

01 Introduction

This guidance provides a practical approach to implementing the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R)[1] and reflects the 2024 amendments.[2] It is intended for all staff groups delivering a range of diagnostic imaging, interventional radiology and diagnostic nuclear medicine services. It also applies to the implementation of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.[3] Unless specifically stated, references to IR(ME)R can also be taken to refer to these Regulations.

Within the UK, responsibility for healthcare is devolved and different approaches may be taken in each of the four nations. The amendments to IR(ME)R 2017 (Great Britain) came into effect in 2024, applicable within England, Wales and Scotland. At the time of publication, the amendments are under review and have not been adopted by Northern Ireland. The amendments reflect good practice and learning from the clinical implementation and enforcement of the Regulations.

Typical scenarios and examples have been included to provide practical advice on aspects of the Regulations. These are informed by examples from hospital trusts and health boards and are illustrative rather than prescriptive. This document should be read in conjunction with IR(ME)R and other published guidance.[4] A glossary of terminology used in this guidance is included in Appendix 1.

The 2024 amendments to IR(ME)R include new requirements relating to the following:

- Introduction of a statutory duty of co-operation between employers when there are multiple employers involved in the delivery of exposure to an individual (Chapter 2)
- Development of employer's responsibilities to ensure appropriate action is taken regarding clinical audit and accidental or unintended exposures (Chapter 3)
- Update to definitions [Regulation 2] to minimise confusion and resolve ambiguity in interpretation
- Update to adequate training [Schedule 3] to improve the content and layout
- Inclusion of software within the equipment requirements, including software that may directly assist an operator in carrying out clinical evaluation (Chapters 11 and 20)
- Development of Schedule 2 to include employer's procedures for the carrying out of clinical audit and appropriate action and procedures for making, amending and cancelling a referral (Chapters 3 and 6).

01
Introduction

The Regulations

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

IR(ME)R places legal obligations on defined duty holders and provides a framework 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.

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	Diagnostic 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-CT (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 • Investigations as part of work-up for organ donation
Non-medical exposures	Individuals undergoing non-medical imaging (NMI) using medical radiological equipment	• Health assessment for employment, immigration or insurance purposes • Identification of concealed objects within the body

02 Duty holder roles and responsibilities

There are four different duty holder roles, each with defined statutory responsibilities in IR(ME)R, as shown in Table 2.1.

Table 2.1: IR(ME)R duty holder roles

Duty holder role	Responsibility
Employer	Responsible for compliance with IR(ME)R and provides framework for written procedures and protocols
Referrer	Provides sufficient medical data relevant to the medical exposure
Practitioner	Justifies the exposure (weighing the benefit against detriment to the individual exposed)
Operator	Carries out practical aspects of the exposure including clinical evaluation

Within this document, any references to the terms 'employer' and 'practitioner' mean the IR(ME)R employer and the IR(ME)R practitioner as defined in Table 2.1 above. Responsibility for compliance with IR(ME)R lies with the employer and each of the entitled duty holders, including 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.

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It is the responsibility of all 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 within a defined scope of practice (eg 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)].

Legal responsibility cannot be delegated. A duty holder 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. Unnecessary delegation has been identified as a known cause of patient safety events and should be avoided; for example, when initiating an exposure, it is best practice to identify the patient yourself rather than delegate.

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. 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 controls supporting them. In practice these are included in systems such as the radiology information system (RIS) and picture archiving and communication system (PACS). Users should have personal passwords as signatories to access these systems, and system entries should be timestamped. Users should be made aware of local procedures governing the use of IT and the General Data Protection Regulation (GDPR),[8] including any potential for disciplinary action if login details are shared or systems are used inappropriately.

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 discussions with individuals exposed
- Quality control (QC) records
- Clear, accurate and up-to-date employer's procedures.

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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] and that where multiple employers are involved, there is co-operation to ensure that all parties are enabled to comply with IR(ME)R. The duties of the employer are set out in Table 2.2.

Table 2.2: 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 4) • Ensure written procedures are complied with by referrers and referrals are made in accordance with referral guidelines and employer's procedures (Chapters 4 and 6) • Establish referral guidelines • Ensure written procedures are complied with by operators and practitioners • Establish written protocols for standard radiological practices • 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) • Share individual dose information between employers (see Chapter 3) • Make available to operators reviewed diagnostic reference levels (DRLs)
Regulation 6A	Co-operation between employers	• Co-operate with employers to ensure each employer has access to information on the exposure (or potential exposure) and is enabled to comply with the requirements of IR(ME)R
Regulation 7	Clinical audit	• Ensure the employer's procedure details how and when clinical audit is carried out and appropriate action is taken, with dissemination of results to appropriate stakeholders (Chapter 3)

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Regulation	Requirement	Things to consider
Regulation 8	Accidental or unintended exposures	• Report, investigate and analyse actual and potential, accidental or unintended exposures ensuring appropriate action is taken (Chapter 21) • Ensure the employer's procedure details how the referrer, practitioner and individual exposed (or their representative) is informed of clinically significant accidental or unintended exposures (CSAUE) and the outcome of analysis of the exposure
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	• Have in place the 16 minimum requirement 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, and 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 should 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 incorporate all 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. Employers must be aware of their responsibilities under IR(ME)R and ensure the tasks they have delegated are appropriately discharged.

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There should be clear governance structures describing how policies, procedures and protocols are implemented and complied with. Employers may wish to establish management structures or committees of responsible staff, such as a radiation protection committee (RPC), to formulate appropriate policies, procedures and protocols, audit and monitor the level of compliance with IR(ME)R, identify remedial action to improve compliance, and keep the employer informed of specific issues that require attention. The committee can also provide a framework for formal adoption of changes to practice and documentation (eg management of equipment procurement and replacement programmes, DRLs, introduction of new techniques, entitlement practices). Where a committee such as the RPC is responsible for the ratification of policies and procedures, employers should consider establishing a mechanism to expedite the process outside the usual meeting frequency to ensure information is up to date. The RPC should feed into the governance framework for providing assurance to the employer of organisational compliance. An organisational chart can be used to demonstrate the governance structure and how it feeds up to the employer. It is important that the membership of the committee accurately reflects all areas and teams within the organisation that use ionising radiation, including duty holders who sit outside the imaging department. For example, membership may include appropriate representation from cardiology, dental and theatres.

Co-operation between employers

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

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

- Outsourcing of services to another employer (either NHS or independent), for example specialist services or specific areas of a service, such as clinical evaluation
- Insourcing of services, for example as part of national or regional initiatives where external staff utilise local equipment and facilities to provide a service
- Utilisation of non-substantive staff, for example third-party providers in the provision of services for the justification of exposures or clinical evaluation or MPE support.

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

Where there is no formal contract in place between employers (eg a GP practice referring to primary care), a co-operation agreement may not be required. However, a level of co-operation will be necessary to comply with IR(ME)R requirements, such as ensuring access to referral guidelines and relevant employer's procedures, and establishing entitlement records.

The employers need to agree and document how each of their IR(ME)R responsibilities is defined and allocated across the exposure pathway. This should include training, competency and entitlement of the duty holders involved in the pathway. Bespoke agreements should be tailored to the services shared between the employers. Appendix 3 gives a list of key things for employers to consider prior to working together.

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The following examples give an indication of the matters that may be considered, but this list is not exhaustive.

- If an employer is outsourcing examinations that meet the local criteria to another employer who will perform the exposure and clinical evaluation, the employer's agreement should state who is performing the justification and authorisation of these referrals and which employer is responsible for their entitlement. The employer's agreement should also specify which employer's procedures, policies and written protocols are being applied to these referrals. The employers should clarify the process to allow access to relevant documentation and patient records and describe how information will be shared. The process to manage referrals, including how to amend and cancel referrals, needs to be specified. The management of patient safety events, including responsibility for reporting, responding, analysing, taking appropriate action and communicating outcomes, also needs to be agreed and documented.
- Another example is the agreement for an employer to provide medical physics support to another employer. The areas described above should be considered within the employer's agreement, and any other relevant matters such as the management and QA of equipment, including handover arrangements, should be included. The employers should consider the processes for audit, including taking appropriate action and communicating results.

When information is shared, employers should confirm that it is accessible and understood. Each employer should ensure shared documentation is agreed, followed and appropriately quality assured.

Scenario 1

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 different 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.

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Referrer

The referrer must be a registered healthcare professional as defined in IR(ME)R.[9] In Northern Ireland, this also includes medical practitioners registered with the Medical Council of Ireland.

Referrers must be entitled, by the IR(ME)R employer, to request that an individual is exposed to ionising radiation as part of a diagnostic, interventional or nuclear medicine investigation. Referrers must follow the employer's procedures. Referrals are made taking into account the referral guidelines made available 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 healthcare professional requesting the exposure must be entitled as a referrer prior to submitting a referral. The employer's procedures must state how referrals are made, amended and cancelled at all points in the patient pathway (ie by referrer and by department). They should also include from whom referrals are accepted, and how the referrer will be provided with the specified referral guidelines and up-to-date employer's procedures. Referrer awareness training is discussed in Chapters 4 and 6. Information on non-medical referrers is included in Chapter 6.

The roles and responsibilities of the referrer are set out in Table 2.3.

Table 2.3: Requirements for the referrer

Regulation	Requirement	Things to consider
Regulations 6(2), 10(1)	Written procedures are complied with by the referrer	• Read and comply with employer's procedures • Ensure referrals comply with employer's referral guidelines • Referrer awareness training (eg process for amending or cancelling a referral) (Chapter 4)
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)	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

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Regulation	Requirement	Things to consider
Schedule 2(b)	Individual entitlement	• Understand specified scope of practice • Adhere to limited referral rights when they are applied • May also include training for referrers (if appropriate), description of the referral process, communication requirements and where to access referral guidelines or further guidance
Schedule 2 (p)	Management of referrals	• Making, amending and cancelling referrals at all stages of the patient pathway

See Chapter 6 for further information on referral guidelines, referrer training, entitlement and scope of practice.

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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.

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. 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 (eg health screening or research) [Regulation 11(2)(b)].

Before justifying an exposure, the practitioner should review the results of any relevant previous investigations 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 2.4.

Table 2.4: Requirements for the practitioner

Regulation	Requirement	Things to consider
Regulation 10(1)	Employer's procedures	• Read and comply with employer's procedures
Regulation 5(1)(b)	Licence for 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 • Seek medical physics support and advice • Co-operate with other specialists and duty holders

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Duty holders

Regulation	Requirement	Things to consider
Regulations 11(1) 11(2), 11(3), 11(4)	Justification of exposure	• Evaluate the information provided including previous exposure history • Consider the benefits and risks of the exposure • Consider the urgency of the exposure • Consider justification of exposures to carers and comforters, asymptomatic individuals and NMI exposures • 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, where required • Retain responsibility for justification of exposures authorised under guidelines
Regulation 12(1)	Optimisation	• Ensure exposures are kept as low as reasonably practicable (ALARP) consistent with the intended purpose • Use non-ionising radiation modalities where appropriate • Be aware of and use local and national DRLs (LDRLs and NDRLs)
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.

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Operator

There is no requirement in IR(ME)R 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 and administration of a radiopharmaceutical
- Image manipulation and archive
- Clinical evaluation
- QC checks of equipment.

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 a named practitioner [Regulation 11(5)].

Automation and artificial intelligence (AI) technologies must only be used in an assistive capacity for the practical aspects of an exposure, as an individual must be involved [Regulation 10(3)]. The purpose and process for any use of AI should be clearly described in the employer's written procedures, including the software's intended purpose, sufficient training, QA and the establishment of performance monitoring. Duty holders using AI should understand its use and limitations and know their roles and responsibilities.

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 2.5.

Table 2.5: 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 or authorisation of exposures to guidelines provided by practitioner • Allocation of responsibility to appropriate specialist staff

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Regulation	Requirement	Things to consider
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 • Request medical physics support and advice
Regulation 12(1)	Optimisation	• Ensure exposures are kept ALARP consistent with the intended purpose • Be aware of and use LDRLs and NDRLs
Regulation 12(3)	Selection of equipment and methods	• Choose the most appropriate equipment and method for the individual being exposed • Ensure exposures are 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, interventional and PET/CT) (Chapter 10) • Pregnancy status (Chapter 13) • Breastfeeding status (Chapter 13)
Regulation 17(1)	Training	• Underpinning knowledge and professional qualifications • Adequate additional training to carry out any practical aspect of an exposure (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 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. Further information on training requirements is available in Chapter 4.

03 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. These are the minimum requirements, and 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 NMI 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 each process. They should include clear instructions on how and when a process should be carried out and who is responsible. Appendix 4 details things to consider for inclusion within the 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 service lead and the MPE, taking into account service delivery and available equipment. Where possible, a local standard template should be considered for these protocols.

An employer's procedure in respect of QA programmes for radiological equipment is also required; more detail can be found in Chapter 20.

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)].

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.

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Employer's procedures

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 (eg 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 • Engagement of 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 software as part of a quality management system (QMS) • 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: review is commonly completed every two to three years or following change in service delivery, legislation or similar, based on whichever is the minimum
How and where can staff access procedures and protocols?	• Read-only electronic documents (intranet, shared network drive or QMS) • 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)

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Employer's procedures

QA programme	Things to consider
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 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, and it should be clear who is responsible for ensuring only the correct version is available.

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.

A robust management system is essential to ensure consistency between written protocols and examination protocols embedded within the equipment. Examination protocols embedded in the radiological equipment require additional management to ensure that they are locked and that changes cannot be made by unauthorised staff. Software updates may change agreed examination protocol settings, so 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.

External review and accreditation schemes for imaging services including QA programmes are available, such as the *Quality Standard for Imaging*.[10] These can be used to support the requirements of IR(ME)R and wider quality standards.

IR(ME)R compliance audit

The QA programme should cover all aspects of the diagnostic imaging process, including practices involving NMI and non-imaging nuclear medicine examinations. To support the management of a QA programme, it can be helpful to establish a rolling schedule of IR(ME)R audits covering each employer's procedure.

As IR(ME)R audits typically measure compliance with the procedures, the target compliance should be set at 100%. This is one aspect where IR(ME)R audits may differ from clinical audits. A blended approach of prospective and retrospective audits may be beneficial to provide assurance in relation to compliance. For example, a retrospective audit of records on the PACS system could identify compliance issues, which could be further explored with an observational type of audit (prospective). Following implementation of audit, outcomes or recommendations for improvement, reaudit of areas of non-compliance within a suitable time frame should be considered. It is important that the knowledge gained from such audits is shared in a timely manner and subsequent actions are identified, recorded and completed in an appropriate time frame.

Some examples of IR(ME)R audits are included in Table 3.2, but this list is not exhaustive.

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Employer's procedures

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

Audit	Things to consider
Employer's procedures	• Do the employer's procedures meet the requirements of IR(ME)R?
Appropriateness of referrals	• Are referrers entitled and referring within their scope of entitlement? • 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? • Is appropriate feedback provided to referrers and corrective actions 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 and appropriate action taken?
IR(ME)R operator, practitioner or referrer entitlement	• Are records up to date and accurate? • Do they reflect current scope of practice? • Are all duty holders appropriately entitled, both within the imaging department and outside (eg GPs)?
Practitioner and operator training records	• Are records available and up to date for all practitioners and operators? • Do competency records reflect available equipment and processes?
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? • Are current LDRLs appropriately displayed or accessible? • Are local dose surveys in place?
Justification and authorisation	• Is it possible to identify the practitioner or authorising operator? • Is the operator authorising appropriately and within the authorisation guidelines?
Clinical evaluation	• Is there evidence of a written clinical evaluation of the exposure in a sample of patient records including those outside the imaging department?

Clinical audit

Regulation 7 requires the employer to have in place a programme for clinical audit. Clinical audit is 'a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change'.[11] Change should be implemented where practice is deemed to fall short of the criteria or standard and, after a specified period of time, reaudited to ensure the corrective action has had the desired positive effect.

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Employer's procedures

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.[12]

A clinical audit will help identify:

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

Schedule 2(o) requires an employer's procedure to be established to describe how clinical audit is carried out and any appropriate actions to be taken following the audit. The clinical audit procedure should describe:

- A clear definition of clinical audit
- The roles and responsibilities for the clinical audit programme
- How clinical audit topics are proposed and selected
- A standard methodology and templates that can be adapted for specific audits
- Where the records of clinical audits are kept
- How findings from audits are measured against established criteria or standards
- How actions are determined and responsibility assigned for completion and reaudit where necessary.

A multidisciplinary team approach to establishing and carrying out an audit programme will yield the most effective results. Further resources are available from The Royal College of Radiologists (the RCR)[13] and example clinical audits are listed below:

- Review of a set number of clinical images to ensure they meet technical requirement standards
- Review of a set of clinical evaluations to evaluate if the report accurately answers the clinical question
- Review of repeat and rejected images to monitor rates against agreed standards.
- Image quality assessment to grade quality of specific examinations to ensure technical adequacy
- Audit adherence to national guidelines for specific examinations, for example iRefer.

Audit reports

Both clinical audit and IR(ME)R audit reports should provide 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. The individuals responsible for carrying out actions should be identified as part of this action plan. Audits should also be used in the engagement, education and training of staff to create an environment of continuous development. Results of audits should be made available to the employer.

04 Training

Regulation 17(1) prohibits any practitioner or operator from carrying out an exposure or any practical aspect of an exposure without having been adequately trained.

Schedule 3 lists the minimum theoretical knowledge and practical experience required as adequate training for practitioners and operators.

Regulation 17(2) defines recognised evidence of training, for example certificates for degrees or diplomas. Regulation 17(3) permits a person who does not have recognised evidence of training to undertake practical aspects of an exposure as part of their training under the supervision of a person who is adequately trained. Where a trainee is undertaking operator duties, this supervision must be direct [Regulation 2].

The training requirements of these Regulations represent the minimum for employers and duty holders to comply with their statutory obligations. There are professional and healthcare regulator education and training standards that expand on these minimum requirements and which individual duty holders must meet. Employers should be mindful of these when considering what is appropriate adequate training for different staff groups.

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 and competency record is included in Appendix 5.

Before operators use any 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 these differences could affect both dose and image quality.

Training is also required in the effective communication of the benefits and risks from an exposure with a patient or other individuals exposed, for example carers and comforters.

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Training

Training records of all staff entitled to act as practitioners or operators should be reviewed regularly, for example as part of the appraisal process. Training records should also be updated as required on a regular basis, for example when additional training has been successfully completed or when scope of practice has changed. This information should be documented and 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. Further detail on employers' co-operation processes is included in Chapter 2. The employing agency has the responsibility to check formal qualifications and registration of the individual through its own recruitment processes. Individual duty holders must ensure they provide accurate and up-to-date evidence of their training and education to new employers. 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

In addition to the requirements of Regulation 17, 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 underpinning 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), introducing new techniques and practices, or adding assistive technology or software. All relevant staff will need to be trained in the use of the new equipment and understand its functions and limitations.

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 patient pathway. Training should include statutory, non-statutory and professional requirements of the individual. 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.[14,15]

MPEs must be appropriately trained and 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

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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 (DHSC) has established a UK-wide MPE recognition scheme and has appointed RPA2000 as the assessing body.[16] The employer must appoint a suitable MPE and ensure they are involved to the extent required by Regulation 14. The scope of entitlement of an MPE operator will be different to the scope of entitlement of an operator undertaking clinical exposures and must be appropriate for their knowledge and skills and the role undertaken; more information on this can be found in Chapter 19. The MPE's unique skill set must be utilised during the equipment procurement process and may involve, for example, discussions with existing users and 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 and exposures they are involved with. As an IR(ME)R operator the MPE should continue to develop their knowledge and skills as required by Regulation 6(3), for example by working with engineers, applications specialists and radiographers during planned upgrades or installations.

MPEs may be expected to work across a wide range of modalities, sites and employers 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. Further detail on employers' co-operation processes is included in Chapter 2.

Clinical technologists and clinical scientists may similarly acquire 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 required 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 type of equipment.

MPEs, clinical scientists 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

Professional qualifications in clinical radiology or nuclear medicine, for example Fellowship of The Royal College Radiologists (FRCR) by examination and the subsequent award of a Certificate of Completion of Specialist Training by the General Medical Council, provide suitable evidence of competence to act as a practitioner.

Employer's procedures should specify training requirements for IR(ME)R practitioners who are not medically qualified, such as radiographers. Consideration should also be given to training requirements for practitioners outside radiology and nuclear medicine such as surgeons or cardiologists. The training records should demonstrate appropriate skills, knowledge, experience and assessed competence within a clearly defined scope of practice. The Society of Radiographers has provided guidance on what should be included in IR(ME)R practitioner training.[17]

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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.[18]

Scenario 2

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, and work within a defined scope of practice. To report these exposures, they are entitled as an operator, and work within the limits of a separate, defined scope of practice. Both training and entitlement records will reflect their additional learning and its application to the clinical setting.

Systems should be in place to develop training competencies, to identify suitably qualified assessors and to support the development of individuals to achieve the level of competence required for their role. Time and resources required to achieve competence will vary according to the individual's learning needs.

Training records should identify the name of the trainee, the competencies achieved, the date the competence was verified and the name of the assessor.

Operator training

Training records for operators should be accurate and up to date, reflecting training and competencies achieved for learned skills. All healthcare staff (including doctors, allied health professionals and the support workforce) acting as operators must have training records that reflect their scope of practice and the equipment they use. Records should be updated to reflect any changes to duties including reduced and extended scopes of practice.

Training records for an operator who is entitled to undertake clinical evaluation should evidence how the individual meets the required legislative and professional standards to interpret the information resulting from an exposure, including the outcome and implications (Chapter 11).

Staff who have not had specific training on working with ionising radiation as part of their professional qualification (eg doctors and nurses) may undertake operator roles after appropriate theoretical and practical training.

An example of this would be a surgeon in theatres using a mini C-arm for orthopaedic extremity surgery. They would be required to meet the employer's training requirements, which would include formal training on using the equipment as well as radiation protection training and completion of training relevant to their IR(ME)R operator responsibilities. The surgeon will need to demonstrate training and competence prior to entitlement as an operator.

All trainees must be supervised by an appropriately trained and entitled operator regardless of professional background. Further detail can be found in the 'Supervision including students and trainees' section below.

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Where operators use remote operating technology, sometimes known as virtual support tools, radiation safety measures must be considered alongside the physical safety and wellbeing of the patient. Employers must ensure operators on-site and in the remote hub are adequately trained before implementing remote operating technologies. A review of local written procedures to clearly identify duty holders' responsibilities is considered essential prior to implementing remote operation.

Scenario 3

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, where applicable, following software updates.

Scenario 4

A radiologist transfers to a new hospital as part of a rotational educational programme and is scheduled to perform a screening list. As part of an earlier placement at a different hospital, the radiologist received equipment training on a similar fluoroscopy unit and was entitled as an operator at that site for screening lists. The radiologist 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 supports their first fluoroscopy session and then completes and updates the 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 directly 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.

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A trainee (eg 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 learning and assessment. Until this time, Regulation 17(3) applies, which permits trainees to perform any practical aspect of an exposure under direct 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.[19,20,21,22] Inappropriate supervision arrangements may put the patient or individual at risk. The same level of care and supervision should apply throughout normal working hours and out of hours.

Where a person carrying out a task is fully trained and competent, 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.

Any operator who does not have the underpinning theoretical knowledge and practical experience from their professional programme of study must provide other evidence of adequate training to the employer. The employer must be satisfied that the evidence supplied meets the requirements of Regulation 17 and Schedule 3 prior to entitling the individual.

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 defined in IR(ME)R. Non-statutory-registered individuals cannot be entitled as an IR(ME)R referrer or practitioner. They can, however, be entitled as an operator once they have been trained and assessed as competent.

Another example of non-statutory registered operators are healthcare science practitioners. Those individuals who have completed a Practitioner Training Programme, or who have demonstrated equivalence with that training programme, are eligible to join an assured Register of Healthcare Science Practitioners through the Academy for Healthcare Science or the assured Register of Clinical Technologists through the Institute of Physics and Engineering in Medicine (IPEM).

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.

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Training for referrers

IR(ME)R does not distinguish between medical and non-medical referrers. The requirements discussed below apply to all referrers regardless of any differences in the training and management of these two groups.

While IR(ME)R does not specify a requirement for referrer training, employers will require referrers to work within their scope of practice.

Regulation 6(2) requires employers to ensure referrers comply with written procedures. It is therefore helpful and considered best practice to ensure referrers complete relevant awareness training. This is likely to be provided by a mixture of online learning platforms and local training. Training may include:

- Use of the referral system
- How to check previous relevant investigations
- How to request, cancel or amend a referral (electronic and/or paper)
- Local procedures governing the use of IT and the GDPR, including any potential for disciplinary action if login details are shared
- How to access referral guidelines, including information on radiation dose
- The specific examinations included in a referrer's entitled scope of practice
- Professional and legal responsibilities.

Referrer training has the potential to reduce the number of inappropriate or repeat examinations by using systems to accurately confirm patient identification at the point of referral. The Society of Radiographers (SoR) has published guidance on preventing patient identification incidents in diagnostic imaging, nuclear medicine and radiotherapy[23] and an IR(ME)R referrers' checklist for referring a patient for a diagnostic imaging examination.[24]

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.[25,26] Enabling equitable access to clinical imaging referrals for registered healthcare professionals working in advancing practice roles provides employers with helpful guidance to ensure the safe and effective entitlement of non-medical referrers.[27]

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

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

Some of the initial tasks related to the 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.

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This should include, for example, familiarisation of the procedure to:

- Confirm the correct identification of the patient
- Alert the referrer when additional information is required
- Alert the referrer when 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 contiguous appointments at appropriate time intervals (eg accurate scheduling of follow-up scans)
- Address patient queries regarding their examination.

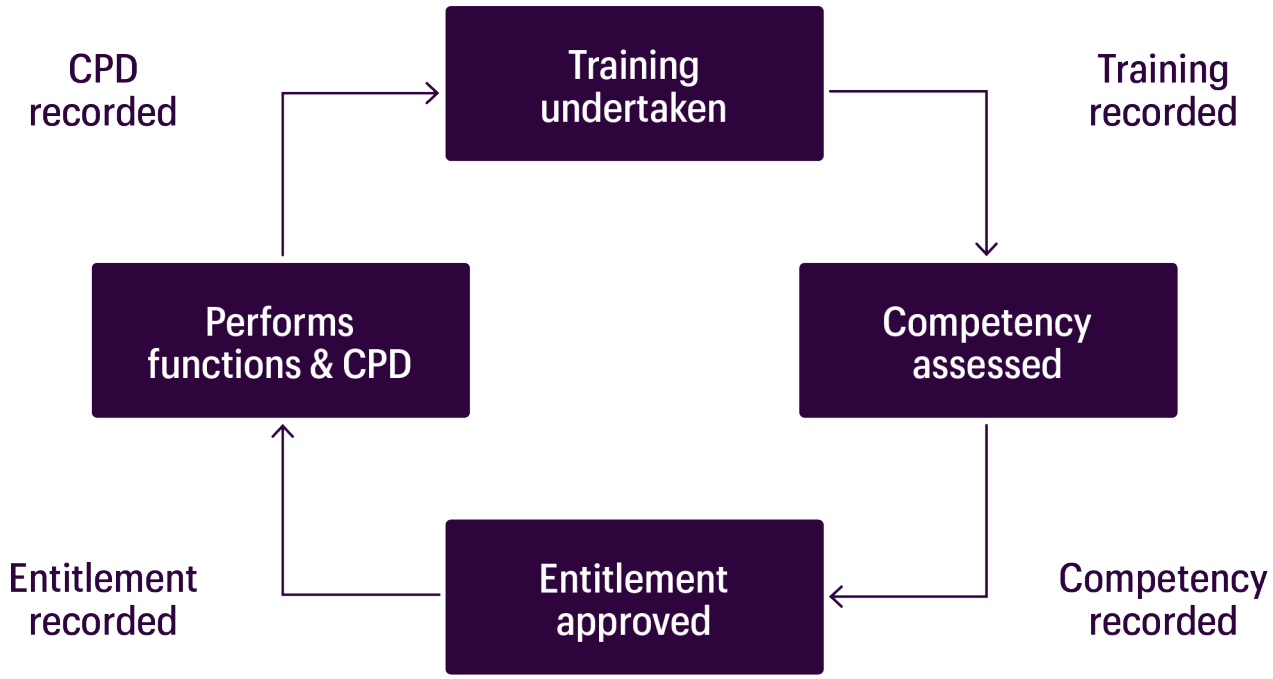
Paper systems and electronic RIS should be fit for purpose, and users should receive training appropriate to their role in the referral to diagnosis pathway.

Referral processes are discussed in Chapter 6.

05 Entitlement

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within the organisation. This duty is often a delegated task from the employer to an individual (or individuals) within the organisation who demonstrates the knowledge and experience to authorise entitlement, on behalf of the employer. Entitlement shows that a duty holder (or a group of duty holders) has been adequately trained and deemed competent in their specific IR(ME)R duty holder role(s).

Figure 5.1: The process of entitlement



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

- Completion of training, supported by training records
- Documented assessment of competence by an appropriate individual
- Entitlement – this may be for an individual or by staff group (when practicable)
- Duty holder performs their functions and undertakes continuous professional development.

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

There is a requirement to have an employer's procedure 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).

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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 the employer and their responsibilities under IR(ME)R
Lines of IR(ME)R accountability and delegation of tasks throughout the organisation	• Clear governance structure • Ensuring tasks are delegated to appropriate individuals • Clear lines of escalation to the employer, where appropriate • Those using ionising radiation or performing duty holder roles (eg clinical evaluation) outside the imaging department
Responsibilities of IR(ME)R duty holders	• For referrers, practitioners and operators reading and complying with the relevant employer's procedures [Regulation 6(2)] • Do staff understand what duty holder roles they are performing and when?
Initial qualification requirements for each duty holder or group of duty holders	• Relevant qualifications (eg FRCR Part 1 for radiologists, BSc (Hons) or equivalent for radiographers, MSc for clinical scientists) • Who is responsible for checking relevant qualifications prior to entitlement?
Confirmation of registration for referrers and practitioners	• Process for checking that individuals are registered healthcare professionals as defined in the National Health Service Reform and Healthcare Professions Act 2002[9]
Confirmation of practitioner licence for administration of radioactive substances	• Records of valid licences, and process for renewal before expiry
How individuals or groups demonstrate their entitlement and scope of practice	• Entitlement letter or documents showing scope of practice and identifying the individual entitled
How entitlement or scope of practice is updated and reviewed	• Process for reviewing and updating entitlement or scope of practice • Specified time frame (eg at appraisal or when scope of practice changes) • Who is responsible for auditing and reviewing entitlement or scope of practice including where entitlement sits outside the imaging department?

Duty holders must be entitled prior to performing the duty holder task; for example, an individual seeking to refer a patient for a medical exposure must be entitled as a referrer prior to submitting the referral. Entitlement may be managed through individual entitlement or group entitlement where appropriate. Where staff are entitled as a group, the employer must be able to identify each individual in the 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 or entitlement matrix from the employer. Operators carrying out examinations must be able to identify the referrer and practitioner for each exposure before it is performed, regardless of how the entitlement is managed (eg individual or group entitlement).

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.

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The procedure must also incorporate those duty holders and areas outside the imaging department where ionising radiation is in use or duty holder roles are performed, such as cardiology, rheumatology services or teleradiology. 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.

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

Scope of practice

A scope of practice describes a range of 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 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 or operators should be reviewed and updated.

The scope of practice may be very limited and specific. For example, a nurse working in a specialist 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.

Scenario 5

The lead radiologist for CT 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 assessed as competent by the supervising radiologist, the competency documentation relating to this training is signed off and is added to the radiographer's training records. Once this has been completed the radiographer may then be entitled, by the employer, to act as a practitioner justifying and authorising these specific CT examinations. The entitlement records are updated with the radiographer's new scope of practice.

06 Referral process

A referral is a request for an exposure to be performed; it is 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 relating to the referral process under IR(ME)R at each step of the patient pathway. These are included in Table 6.1.

Table 6.1: Considerations for the referral process

Regulation	Things to consider
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[28] • Consider developing local referral guidelines for specialist pathways, or those not included in iRefer • Include radiation dose information • Process to ensure all referrers have access to referral guidelines (including referrers external to the organisation)
Employer must establish an employer's procedure for making, amending and cancelling a referral Regulation 6 Schedule 2(p)	• Outline how the referrals are made; this can be paper based or through use of electronic systems; consider mandatory fields to reduce incomplete referrals • Communication process for amending and cancelling referrals[29] • Management of incomplete or inappropriate referrals • Process to ensure referrers recognise any limitations due to their scope of practice and understand how this aligns to their responsibilities under IR(ME)R
Referrer must comply with the employer's procedures Regulation 10(1)	• Process to ensure all referrers have access to the employer's procedures (including referrers external to the organisation) • Audit quality of referrals against referral guidelines (including shared learning)
Referrer must supply sufficient medical data for practitioner to enable justification Regulation 10(5)	Information that should be included on a referral: • Accurate, up-to-date patient identification information (eg date of birth, current address, full name) • Requested examination, including anatomical area and laterality (where applicable) • Relevant previous clinical history, including current symptoms and previous imaging • Pregnancy status (where relevant) • Breastfeeding status (where relevant) • Carer or comforter requirements • Referrer name, contact details and signature • Date of referral completion

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Referral process

Regulation	Things to consider
	• Information related to research trials (where relevant) • Deferred date for examination to be completed (where relevant) • Mobility status (eg requires hoist) • Co-morbidities (where relevant) • Medication (where relevant) • Other relevant radiation protection information
Practitioner must consider information supplied by referrer to justify each individual exposure and avoid unnecessary exposures Regulation 11(4)	• Process for contacting referrer for additional information or where urgent or critical findings need to be communicated • Documentation of discussions with referrer • Process for declining, cancelling or amending referrals

The referrer must supply sufficient medical data (eg previous diagnostic information or medical records) to enable the practitioner to weigh up the benefit of the exposure against the risks (ie justification) [Regulation 10(5)]. Referrers should avoid the use of acronyms unless defined and agreed locally. Further information on the justification process is included in Chapter 7.

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

Referral guidelines

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

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 specialist examinations are undertaken that are not included in iRefer, referral guidelines must be developed and implemented.

In nuclear medicine and PET-CT, British Nuclear Medicine Society (BNMS) guidelines, European Association of Nuclear Medicine (EANM) guidelines and the PET-CT evidence-based guidelines are often used for the development of referral guidelines.[30,31,32]

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Referral process

Employer's procedures

The referrer must comply with the employer's procedures [Regulation 10(1)]. The employer must ensure that the current version of the employer's procedures is made available to all referrers, including those external to the organisation. There should be a process to ensure referrers understand their responsibilities under IR(ME)R and the employer's procedures.

Schedule 2(p) requires a procedure that outlines how referrals are made, amended and cancelled. This procedure should detail the responsibilities of the referrer, how referrals are made, what information must be included, how referrals can be amended or cancelled and the appropriate communication requirements. Audit is a valuable tool to assess compliance with the employer's procedures.

Referrer training

While not explicitly required under IR(ME)R, it is considered best practice that, where practicable, referrers complete some form of local radiation safety and referral procedures awareness training. A resource to encourage referrers to pause and check prior to making a referral was introduced in 2017.[24] More details on referrer training can be found in Chapter 4.

Referral systems and processes

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. It is important that the referrer is clearly identifiable, regardless of the type of system in use.[33] Where the initial receipt and processing of referrals is undertaken by non-IR(ME)R duty holders such as administrative staff, consideration should be given to relevant training requirements. This includes ensuring referrals are actioned in a timely and consistent manner, the identification of duplicate referrals and ensuring primary source data (original referral) are available throughout the patient pathway.

Electronic referral systems require the referrer to log in using a unique identifier. Employer's local procedures should state that users must not use someone else's login to initiate a referral and describe any potential consequences and actions. 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. 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 Care Quality Commission (CQC) has reported that the most commonly notified referral error is the 'wrong patient' being referred for imaging.[34]

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]

As part of an inclusive safety culture, the referrer should be notified and given the opportunity to contribute to investigations relating to any error or near miss involving an incorrect or inaccurate referral they were involved in.

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Referral process

Non-medical referrers (NMRs)

There are several groups of registered healthcare professionals who are not medically qualified but, as part of their extended role, may request to be entitled to act as a referrer. They are known as non-medical referrers (NMRs). The process should start with establishing the service need and lines of accountability involved in a non-medical referral pathway.

- The criteria for entitlement should be agreed locally by the service accepting referrals and entitling the NMRs.
- The process should describe the training programme, competency sign-off and audit processes to be completed before entitlement would be granted.
- A formal application may include the reason, scope of practice and service delivery improvement this individual will provide for the organisation.
- 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. The standards and evidence of training should be established prior to the NMR pathway being implemented.[27] Training may be delivered via an educational institution, in-house or by e-learning or a combination of all approaches. Examples of theoretical and practical training are listed in Table 6.2. NMRs should complete relevant update training on a regular basis (eg at least every three years). Individual NMR entitlement should only be granted once documented training evidence is provided and the requirements have been met. If it is reported, or audit demonstrates, that an NMR is repeatedly acting outside of their agreed scope of practice, refresher training may be required, or their entitlement reviewed.

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, and systems should be in place to remove entitlement for individuals who are no longer employed, no longer meet the requirements of their role or repeatedly fail to comply with the employer's procedures.

All referrer duty holder requirements of IR(ME)R apply to NMRs.[25]

NMRs may be:

- 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 different 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. In this case the advanced nurse practitioner must also be educated, trained and entitled as an IR(ME)R operator to make the clinical evaluation.

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Referral process

Table 6.2: Examples of theoretical and practical training for NMRs

Training type	Examples of training to be undertaken
Theoretical	• Principles of radiation protection • Biological effects of ionising radiation • Legal and professional responsibilities • Responsibilities in relation to patient safety and clinical governance • Benefits and risks of examinations, including radiation doses, 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

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.

Defining appropriate scopes of practice for referrers

Employers should be aware that some professional bodies may recommend restricting or limiting scopes of practice in relation to IR(ME)R roles for registered professional groups. For example, the Royal College of Nursing has issued guidance stating that nursing associates are not eligible to be IR(ME)R referrers due to the nature of their roles.[26] Recommendations should be taken into account when defining scopes of practice for local referrers. Employers may limit applications for a referral scope of practice that do not reflect nationally agreed professional standards or do not meet the needs of local services or care pathways.

Scopes of practice may change over time and a robust process for the review of entitlement needs to be established. A defined periodic review should include confirmation of professional registration and continued relevance of the scope of practice in relation to the duty holder's role.

07 Justification and authorisation

Justification and authorisation are two separate processes, both of which must be completed before any exposure is carried out.

Justification

Justification is the intellectual 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. Justification can only be completed by a suitably entitled IR(ME)R practitioner.

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

Justification must be performed for each individual exposure that applies under IR(ME)R, including:

- 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 NMI using medical radiological equipment.

When justifying an exposure, there are several factors for practitioners to consider. 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 individual?
- 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.

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Justification and authorisation

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 that involves the administration of radioactive substances to an individual who is breastfeeding, the urgency of the 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.

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	• How may the exposure outcome affect the care pathway or management of the individual? • Previous imaging, medical history, age and body habitus • Pregnancy or breastfeeding status • 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 or management 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 time frame? • If no effective alternative techniques are available, what is the risk of not having the exposure?

There may be circumstances where more than one practitioner is involved in the justification process. The following scenario demonstrates where more than one practitioner is responsible for the justification of different elements of the examination.

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Justification and authorisation

Scenario 6

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 a different practitioner, who justifies and authorises the additional CT exposure.

Authorisation

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

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

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

Scenario 7

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 local 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, documents the verbal authorisation and includes the details of the radiologist as the justifying practitioner.

Authorisation guidelines

Authorisation guidelines are documented criteria that allow entitled operators to authorise exposures when the practitioner is not available or to facilitate more timely patient pathways.

The operator is responsible for authorisation and for following the authorisation guidelines accurately. Authorisation guidelines must be issued by one named practitioner. The practitioner who issues the authorisation guidelines takes responsibility for justification of each individual exposure authorised by operators following these guidelines. If this practitioner leaves the organisation's employment, the guidelines must be reviewed and updated by another practitioner, who then takes the responsibility for the exposures authorised under their guidelines. The practitioner and review or revision dates should be clearly stated.

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Justification and authorisation

The authorisation guidelines should reflect current best practice and take into account local service provision. Authorisation guidelines should be clearly written using precise statements that are unambiguous to allow the operator to confirm whether the referral can be authorised. Authorisation guidelines typically outline the applicable patient cohort (eg adult or paediatric patients), clinical indications or clinical query, exclusion criteria and the standard required imaging protocol or technique. 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. In this scenario, justification and authorisation must be performed by a practitioner. As the intellectual task of justification of the examinations listed in the authorisation guidelines has been carried out by the issuing practitioner, the guidelines cannot ask the operator to consider alternative modalities.

In a hospital that has several 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. It must be possible to identify who the individual practitioner is for each exposure performed and who has authorised the exposure.

Scenario 8

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, assessed as competent and act within their defined scope of practice. 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.

Scenario 9

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

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Justification and authorisation

the exposure; it is important to identify the individual authorising 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 of their entitlement and may be in breach of IR(ME)R and the employer's procedures. Registered healthcare professionals can only legally function as practitioners if they are entitled to do so.

Entitlement by the employer infers a level of protection for both the employer and employee; the employer is assured that employees are working within a defined and agreed scope of practice, and employees cannot be expected to do anything for which they are not entitled or trained.

Non-IR(ME)R terminology

There are a number of activities that occur prior to performing the exposure. These activities may relate to scheduling the appointment, prioritising urgency, applying protocols, justification and authorisation, or reviewing previous imaging. Non-IR(ME)R terminology such as 'vetting' and 'protocolling' is sometimes used to describe some of these activities and can mean different actions for different departments.[29] If alternative terminology is to be used, the employer's procedures must clearly describe what actions the terms refer to.

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 and 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 and comforters.

Table 7.2: Additional considerations for exposures to carers and comforters

IR(ME)R Regulation 11(3)(b)	Things to consider
(i) Any likely health benefits to the patient being examined	• Possibility of having someone they trust with them during a diagnosis or treatment
(ii) Any possible benefits to the carer or comforter	• Reassurance that a family member, partner, friend or dependant is being cared for safely and appropriately 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?

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Justification and authorisation

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 (eg NHS Breast Screening Programme) or as part of an individual health assessment (IHA).[36] 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. An example of good practice is where local procedures stipulate exposures to asymptomatic individuals are individually justified and authorised by the practitioner, rather than including these criteria in authorisation guidelines. The practitioner must take into account recommendations and guidance from relevant bodies, for example the UK National Screening Committee.[37]

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. Each research exposure requires justification and authorisation.

Justification for non-medical imaging exposures

An employer's procedure [Schedule 2(m)] is required for NMI exposures. Regulation 11(1)(e) requires that NMI exposures must comply with the employer's procedures for this group of exposures. The employer's procedure should specify which NMI exposures, if any, are undertaken by the organisation and how each group of non-medical exposures is identified and managed. For example, it may be decided that non-medical exposures must be individually justified by a practitioner rather than falling under broader authorisation guidelines issued by the practitioner. Each non-medical exposure requires justification and authorisation taking into account the considerations detailed in Table 7.1. Further information on NMI exposures can be found in Chapter 18.

08 Optimisation

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

The optimisation process is the joint responsibility of the practitioner and operator, with involvement as appropriate from the appointed MPE. Regulation 12(1) requires the practitioner and the operator to ensure that doses are kept ALARP consistent with the intended purpose of the exposure. Regulation 14(3) requires the MPE to contribute to optimisation of exposures to patients and other individuals.

The aim of optimisation is to achieve the image quality required to answer the clinical question using the lowest dose possible. Optimisation is not limited to dose reduction; it requires an understanding of image quality, equipment parameters and their intercorrelation. Therefore, optimisation requires a multidisciplinary approach with input from specialists able to advise on all aspects of the imaging chain.

To achieve this, imaging services should consider the establishment of a multidisciplinary team of radiation protection champions including MPEs, radiographers and radiologists. The team may cover a range of modalities or have a single modality focus. The responsibility of this team should be to establish the processes for dose management within the organisation and to evaluate and effectively communicate the outcomes of those processes. Efficient working practices are important to ensure the team works effectively towards optimisation. A formal record of meetings will ensure any actions are expedited and followed up. Considerations regarding the establishment of such a team are shown in Table 8.1.

Table 8.1: Establishment of a multidisciplinary optimisation team

When establishing team	Things to consider
Roles and responsibilities	• A **leadership sponsor** such as the head of department who owns and enables the project, for example by ensuring allocated time is available and ensuring that objectives are well defined, measurable and time limited • **Team members** such as radiologists, radiographers and medical physicists with multidisciplinary experience and expertise; additional specialists may also be invited from time to time as required • A member of the team to be established as the **team leader** • Terms of reference should be in place to show aims, objectives and proposed outcome of the meetings • A formal record of meetings should be kept capturing the action plans drawn up
Programme objectives and measurable outcomes	All should agree on: • The vision of the dose management work • The goals to be achieved • The metrics to be used to measure the goals • Timescales and regular review periods

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Optimisation

When establishing team	Things to consider
Frequency of meeting	• The team should establish a regular meeting programme; this may be more frequent towards the start of the project in order to establish the scope of work and action plan
Examples of activities the team may undertake	• Optimisation and consistency of imaging protocols • Dose audits and establishment of DRLs • Review of training programmes and content • Setting of dose limit warnings for high-dose procedures • Optimisation following the installation of new or updated equipment • Introduction and optimisation of new techniques and protocols

Optimisation should be an ongoing process and include when practice changes or when equipment is updated. The optimisation process should be considered and included in staff training. Table 8.2 describes areas for consideration when carrying out optimisation, but this list is not exhaustive.

Table 8.2: Optimisation – areas to consider

Optimisation	Things to consider
Protocols Regulation 6(4)	• Written protocols are in place for all standard examinations, including NMI and research exposures
Clinical audit Regulation 7	• How image quality, technique, protocols, doses or reject analysis may be audited and practice changed based on evidence
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), 14(3)(a)	• MPE to be consulted on optimisation, including patient dose assessment, radiation protection of patients and other individuals, and DRLs (Chapter 19)
QA Regulations 6(5), 12(3), 15(1)	• There are established QA programmes for both written procedures and equipment or methods
Training Regulation 17(1)	• There is a robust training programme in place to ensure all practitioners and operators are competent and aware of how to optimise exposures for existing, new or updated equipment
Carers and comforters Regulation 6(5)(d)	• Adherence to dose constraints specified in employer's procedures
Medical or biomedical research programmes Regulation 12(4)	• Informed consent to be given by the individual or on their behalf, as appropriate • Informed in advance about the risks of the exposure • Establishment of and adherence to relevant dose constraints • Planning of individual target levels of dose by the practitioner with input from the referrer as required

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Optimisation

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

Table 8.3: Areas requiring particular attention when optimising exposures

Particular attention when optimising	Examples of things to consider
Exposures of children	• Appropriate operator training in paediatric technique and exposure setting • A minimum set of programmed protocol settings (eg based on a range of ages and weights) • Specific paediatric imaging protocols for nuclear medicine, administered activity scaling and specified minimum activity • Additional local training on paediatric imaging techniques
Exposures in a health screening programme	• Establish the standards and specific inclusion criteria in line with those approved by the UK NSC • Robust QA programme • Regular image quality audit against the standard
Exposures involving high doses (eg fetal doses >10 mGy), examinations exceeding minimum threshold for tissue reactions (eg cataracts, erythema), some hybrid imaging (eg 18FDG PET-CT), some CT interventional procedures	• Specialist optimisation training for staff involved in high-dose examinations • Use of pre-programmed dose limit warnings and other available automated dose management systems • Regular review of protocols • Audit of image quality • Dose surveys
Individuals where pregnancy cannot be excluded	• Referral pathway (eg consultant to consultant) • Provision of adequate information related to the benefits and risks and valid informed consent obtained • Minimise scan area to keep dose ALARP • Administer a lower activity and increase image acquisition time
Individuals who are breastfeeding	• Provision of adequate information related to the benefits and risks • Consider delaying examination; alternative radiopharmaceuticals; interruption of breast feeding

While examination 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 are likely to 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 protocols is considered good practice. In nuclear medicine, 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.

09 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 (eg CT, fluoroscopy or general radiography) [Regulation 2(1)].

DRLs are often considered the first step in the optimisation process. 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. All operators should be familiar with and trained in the appropriate use of DRLs.

DRLs are generally set following national and local surveys (referred to respectively as NDRLs or LDRLs). 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.[38] They can help to identify issues relating to equipment or practice by highlighting unusually high or low radiation doses. DRLs should be used with professional judgement and should not consistently be exceeded in normal practice.

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 (DR, CR)	Dose area product (DAP)	$Gy.cm^2$
Fluoroscopy, including interventional	Fluoroscopy DAP	$Gy.cm^2$
	Acquisition DAP	$Gy.cm^2$
CT	CT dose index (CTDIvol)	mGy
	Dose length product (DLP)	mGy.cm
Mammography	Mean glandular dose	mGy
Nuclear medicine	Administered activity	MBq
		MBq/kg

Where different pieces of equipment (within a modality) use different coefficients of units, it may be beneficial to reflect these in the DRLs.

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 considered.

Paediatric populations vary and DRLs will need to consider a range of ages and weights. Weight is generally considered as the most suitable approach for establishing paediatric body DRLs, although age is sufficient for paediatric head DRLs. Further guidance on establishing paediatric DRLs is available.[39]

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DRLs

In nuclear medicine, the DRL is the administered activity. LDRLs in nuclear medicine should specify a tolerance on the activity to be administered (eg ±10%) for each examination. For some nuclear medicine examinations (eg myocardial perfusion scanning or PET-CT), LDRLs 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 NMI using medical radiological equipment. If a department performs an adequate number of standard interventional procedures, a DRL for those procedures should be established. LDRLs should be set with regard to national and international DRLs where available and the rationale for any differences recorded.

National DRLs (NDRLs)

While international DRLs are available, NDRLs better reflect UK equipment and practice. All UK diagnostic and interventional NDRLs are adopted and published through a process established by the UK Health Security Agency (UKHSA) NDRL Working Party.

NDRLs for administered radioactivity in nuclear medicine examinations are set by the Administration of Radioactive Substances Advisory Committee (ARSAC).[18] These are the recommended administered activities for standard-size patients.

National dose surveys or audits may be undertaken by UKHSA or ARSAC, professional bodies or other suitable organisations.[40] Resultant data, suitable as NDRLs, are presented to the working parties for their consideration.

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, including when new equipment is installed and if clinical practice changes, as advised in IPEM guidance.[41] 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. LDRLs should be developed for commonly requested examinations for children.

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

Employers, 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.[41] Where an LDRL is set higher than the NDRL, based on a local dose audit, this should be justified by the employer. In this scenario, efforts should be made to optimise further, or consideration given to replacement of equipment. Having the LDRLs displayed in the work area is considered good practice.

09

DRLs

Scenario 10

A radiology department has recently installed a DR 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 are 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 RPC. The room DRL chart is updated to reflect the newly agreed values, and staff are informed of the change.

Scenario 11

A nuclear medicine department has set an LDRL of 600 MBq ± 10% for a two-day myocardial perfusion imaging protocol using 99 mTc tetrofosmin. An audit of administered activities from the past six months shows that the distribution is skewed towards the upper limit of the tolerance range with the average activity administered 635 MBq. The MPE is contacted and further analysis of the administered activity is carried out including assessment of residual activity, correlation of administered activity with patient weight and assessment of image quality. Following this analysis, a weight-based activity schedule is proposed and ratified by the RPC.

In nuclear medicine, it may be possible to set an LDRL at a lower administered activity than the NDRL. The NDRL may be exceeded for individual patients where clinical circumstances make it necessary, for example patients who are overweight or 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.[18]

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 (eg 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.

DRLs should be reviewed systematically, preferably by a multidisciplinary team consisting of, for example, radiographers, technologists, radiologists, interventionists and MPEs. Consideration should be given to including duty holders who sit outside the standard radiology structure such as surgeons and cardiologists.

This function may be undertaken by the multidisciplinary optimisation team, where doses, protocols and processes can be reviewed in a structured way. A formal record of these team meetings will ensure any actions are expedited and followed up.[42]

09

DRLs

Scenario 12

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 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 that 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 collated and assessed when:

- Establishing LDRLs
- Undertaking incident analysis
- Comparing and standardising protocols between equipment
- Performing audits
- Collecting dose estimates as required under Regulation 13
- Optimising protocols
- Establishing dose constraints.

This can be achieved by recording parameters relevant to each exposure. The parameters to be recorded can be found in Chapter 9.

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 employers to have a procedure for the assessment of patient dose [Schedule 2(e)]. The employer's procedure should specify what information needs to be recorded for each type of exposure as this may be different for each modality and can vary from one piece of equipment to another. The employer's procedure should also specify where the dose indicators are recorded, including where equipment sits outside the imaging department. 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 DAP or DLP. Facilities for dose mapping significantly improve the ability to identify such cases and should be considered if available. 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, with appropriate advice from the practitioner, should discuss the benefits and risks of the exposure, including the radiation effects that may occur. More information is included in Chapter 14.

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.

10 Patient dose

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 RIS or 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 • Capacity to transfer this information to the individual's record, where appropriate and practical

Generally, equipment will display a dose indicator, which is dependent on the modality; this must be recorded on the patient's record of exposure 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 is helpful to record the weight of the individual for inclusion in dose audits.

11 Clinical evaluation

Regulation 12(9) says that the employer must ensure that a clinical evaluation, including the outcome and implications, is recorded for each exposure. Clinical evaluation involves the assessment of an image or test results and the associated 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.

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.

Any assessment of an image or test result following a radiation exposure that has an impact on patient management should also be considered a clinical evaluation. The individual performing this task must be trained and entitled as an operator. This also applies to the clinical evaluation of exposures that take place outside of the diagnostic imaging, interventional radiology and nuclear medicine departments. The outcome of the clinical evaluation may be recorded directly in the patient's electronic records or written clinical notes.

Where technical reports are generated following an exposure (eg non-imaging nuclear medicine studies or DXA imaging), these reports must be clinically evaluated by an operator and a formal report issued.

Scenario 13

A patient's blood samples for a glomerular filtration rate (GFR) investigation are assayed in a sample counter within a nuclear medicine department. The results from the sample counter are entered into a GFR calculation spreadsheet by an operator. The nuclear medicine physics department then analyses the results and produces a GFR value. The process of clinical evaluation is not complete until this GFR value is checked against the normal range and the GFR value, and how this compares to the normal range, is formally reported and linked to the patient's record, for example on the RIS.

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 process of clinical evaluation, and adherence to the employer's procedure, should be assessed by audit[43] (see Chapter 3). Clinical evaluation is the final step in the justification process. Exposures that are not clinically evaluated are not justified.

11
Clinical evaluation

Scenario 14

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, in 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. Patient notes are audited at regular intervals to ensure compliance with the recording of clinical evaluation outside radiology.

Scenario 15

An orthopaedic surgeon performing a hip-pinning procedure in theatre requires fluoroscopic guidance to accurately position the pins. Following completion of the operation, the surgeon (who is entitled as an operator) records the clinical evaluation in the patient's postoperative notes. The radiographer operating the equipment 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.[43] Recommendations on alerts and notification of imaging reports have also been published.[44] 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 (eg GDPR)
- Communication system for discussion of findings, including an escalation procedure for urgent clinical findings
- Audit programme.

Use of AI in clinical evaluation

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

In accordance with the Regulations, AI tools can be used to assist operators in the prioritisation, interpretation and decision-making aspects of clinical evaluation. Operator training on software used to support decision-making as part of clinical evaluation should be recorded to demonstrate competency prior to entitlement. This would be in addition to the required training and competency for clinical evaluation.

11

Clinical evaluation

Details of any software used to directly assist clinical evaluation must be held within a software inventory. Based on intended use, acceptable performance criteria should be set, including systems to measure effectiveness and action improvements.[45,46,47] AI software must meet robust clinical validation criteria and be used within its intended purpose. The employer and operators should be aware of the limitations of AI software, any changes due to major updates and other factors that may impact the software performance.

Scenario 16

Advanced nurse practitioners and doctors based in the emergency department perform clinical evaluation of radiographs prior to determining the treatment of the patient. These staff groups have been appropriately trained, assessed as competent and entitled as operators to perform the task of clinical evaluation relevant to their role.

The hospital has introduced AI software to support clinical evaluation within the emergency department. The intended purpose of the AI software is to highlight regions of interest in terms of potential fracture on radiographs. The relevant operators received training in the use of the AI software as a support tool, the software limitations and factors that may affect the performance of the software. The relevant procedures were updated to reflect the role of the AI software.

When performing clinical evaluation in the emergency department setting, operators use the AI software as a diagnostic aid. Operators should clinically evaluate the complete study and all associated images. The clinical evaluation is documented in the patient notes in accordance with the employer's procedures.

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.

Positive patient identification means correctly identifying the individual to be exposed to ensure they receive the exposure intended for them. All duty holders must understand their role in the correct identification of the individual to be exposed. Correct identification always starts with the referrer. Prior to any exposure correct identification (ID) of the patient or individual to be exposed must be undertaken and is an operator task.

Robust employer's procedures should be in place to ensure the individual can be correctly identified in any clinical scenario. These should be supported by fit-for-purpose standardised information technology systems and infrastructure.

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. It is advised as a minimum to ask the following questions:

- What is your full 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 or missing identifying information.

Professional body guidance and resources are available to assist organisations to implement robust policies for the process of identification.[23,48] There are a number of additional checking processes suggested by professional bodies such as, but not limited to, checking previous imaging and confirming laterality or anatomy.[49,50] 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.[51,52,53]

The operator undertaking the individual identification check must be identifiable by their signature on the referral or electronically. 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 and how this is documented or recorded. The operator undertaking the exposure must be assured the individual has been correctly identified before proceeding with the exposure.

Risk of misidentification is higher when patients are transferred between healthcare providers or organisations.[50]

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Identification of individual

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 individuals or patients	• Use hospital wristband as part of ID check • Cross-reference hospital 'unknown patient' number and major incident policies • Use national unique patient identification (NHS) 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) and how the operator can evidence this • 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 rather than a family member
Paediatric patients	• 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 requirement for theoretical knowledge and practical experience in the identification of the individual being exposed for all operators working in diagnostic radiology, radiotherapy and nuclear medicine.

In nuclear medicine, Schedule 3 requires training on preparation of individual doses of radiopharmaceuticals, and 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, those individuals who are breastfeeding and breastfed infants. 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: Regulatory requirements relating to pregnancy and breastfeeding

Regulation	Things to consider
Procedure to establish pregnancy and breastfeeding status Schedule 2(c)	• Specify examinations where pregnancy and breastfeeding enquiries are relevant • Exceptions where pregnancy checking is not required • Specify the cohort of individuals where pregnancy and breastfeeding enquiries are required • Specify the age range for pregnancy and breastfeeding enquiries based on local demographics • Define local high fetal dose procedures (eg greater than 10 mGy) • Process to follow if local decision-making process requires pregnancy testing • Process if more than one operator is involved in an exposure • Process for patients outside of radiology (eg theatres) • Unconscious patients and emergency situations • Individuals lacking capacity and those with sensory impairment • Process for how enquiries are recorded • Process for the exposure of pregnant or breastfeeding individuals • Process when pregnancy is disclosed in individuals aged under 16 (including support and safeguarding where appropriate*)
Measures to raise awareness Regulation 6(8)	• Specific and sensitive information to explain the need for pregnancy and breastfeeding status enquiries • Posters and leaflets in waiting areas • Information in appointment letters and documentation for wards • Adequate training for those involved with patient communication
Justification Regulation 11	• Availability and appropriateness of alternative examination involving less or no ionising radiation • Urgency of the examination and whether it could be delayed • Consultant-to-consultant referrals for high-dose or complex exposures on children and young adults or where an individual is pregnant

13 Pregnancy and breastfeeding

Regulation	Things to consider
Optimisation Regulation 12	• Optimised protocols for pregnant individuals • Adequate operator training (how to adjust technique or protocols) • Reduce administered activity and image for longer where possible

* 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.[54,55,56]

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). Referrers may only disclose an individual's gender history to another healthcare professional when it is directly related to their care, and they must gain the patient's consent to do so. This relates to individuals registered as male on a healthcare system who were assigned female at birth and therefore have childbearing potential.

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 with childbearing potential 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)].

Some individuals may be fearful of initiating conversations about pregnancy for reasons such as abuse, cultural sensitivities and previous experience of discrimination. Schedule 3 requires adequate operator training in risk communication.

13

Pregnancy and breastfeeding

Employer's procedure

Age range

Pregnancy enquiries are usually made for examinations on individuals of childbearing potential within the age range 12–55 years. However, liaison with the local trust or health board obstetrics team is recommended to set an age range that more accurately reflects local demographics (eg 10–55 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.[56] 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.

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. The operator must confirm pregnancy enquiries have been undertaken and documented. Interventional procedures may include the use of additional documentation such as the WHO checklist.[51]

National Institute for Health and Care Excellence (NICE) clinical guideline 'Routine preoperative tests for elective surgery' recommends enquiring about the possibility of pregnancy, providing information relating to the risks to the fetus, documenting conversations and carrying out a pregnancy test, with consent, if there is any doubt.[57]

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 by the practitioner.

Trans and gender-diverse people

A trans or gender-diverse person is someone whose gender identity differs from the sex they were assigned at birth. Some trans and gender-diverse people who were assigned female at birth may have the potential to become pregnant. The legal process for gender recognition in the UK is set out in the Gender Recognition Act 2004.[58]

Consideration should be given to the employer's procedure to ensure it complies with all relevant legislation and reflects the diversity of the gender spectrum in the population when making pregnancy enquiries.[59] The employer's procedure should be in keeping with the wider trust or health board policy on patient dignity and privacy. Tools such as information leaflets, posters and patient questionnaires can be used to facilitate effective communication.

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

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Pregnancy and breastfeeding

Considerations when making pregnancy enquiries

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

Table 13.2: Considerations when making pregnancy enquiries

Scenario	Additional things to consider
Referrer	• May not have asked the individual prior to referral or may not have the individual's consent to share the information
Individual	• May not be aware they are pregnant • May be afraid of sharing this information
Specific communication needs	• Individuals lacking capacity • Individuals with sensory impairment • Individuals who speak an alternative language • Sensitivity for individuals undergoing medical treatment that may affect fertility • Sensitivity and appropriate language for gender-diverse individuals
Variable cycle menstrual periods	Menstrual cycle may not be regular: • Affected by illness • Affected by chemotherapy treatment • Affected by other medical therapies that can disrupt menstruation
Parent, guardian(s) or partner present	• Individual unwilling or afraid to answer
Underage sexual activity	• Legal consequences for those under 16 years (include in local safeguarding processes)
Concealed pregnancy	• Vulnerable individuals
Religious or cultural beliefs	• Individual unwilling or afraid to answer
Trans or gender-nonconforming individuals	• Use of appropriate language

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, duty holders should consider:

- 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 1 mSv.[18]

Practical application

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

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Pregnancy and breastfeeding

Table 13.3: Possible actions to consider

Response	Examples of possible action
No possibility of pregnancy	• Proceed with the examination
Pregnant	• Inform practitioner of pregnancy status Practitioner reviewing the justification should consider the following: • Discuss with the referrer if the exposure can be deferred or if another examination that involves less or no ionising radiation is appropriate • Re-evaluate the benefits and risks of the exposure to the individual and fetus • If proceeding, where possible seek MPE support to further optimise the potential exposure of the fetus
Pregnancy cannot be excluded low-dose examination (eg fetal dose below 10 mGy)	• Determine whether the individual's period is overdue • If their period is not overdue then continue with the examination • If their period is overdue, or they report a missed period, they should be considered pregnant (see pregnant response above)
Pregnancy cannot be excluded high-dose examination (eg fetal dose above 10 mGy)	• Determine whether the exposure falls within the first 10 days of their menstrual cycle • If within the first 10 days, proceed with the examination • If outside the first 10 days, they should be considered pregnant if pregnancy cannot be excluded, for example by pregnancy test (see pregnant response above)

An example of a pregnancy enquiries flow chart can be found in Appendix 6. If a flow chart is used locally to support operators, this should reflect the local employer's procedure.

The use of pregnancy testing within an imaging department can raise complex issues that should be considered when drafting the employer's procedure. Guidance is available on the use and accuracy of pregnancy testing.[56,57,60]

If pregnancy testing is undertaken for high-dose examination where pregnancy cannot be excluded, the employer's procedure should specify:

- The required practitioner involvement in the decision to undertake pregnancy testing
- Which test is most appropriate (eg urine or blood)
- Who carries out the test
- The training required to perform the test, interpret the results and inform the patient
- The facilities (including time) required to do so.

It must be documented that the pregnancy and breastfeeding enquiry has been made and evidence provided 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.

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.

13 Pregnancy and breastfeeding

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. Where pregnancy is known and the exposure is required, MPE support should be sought to further optimise the potential exposure of the fetus. In all cases, there is a requirement to follow procedures.

All duty holders have a responsibility for the radiation protection of the fetus or breastfed 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.[61]

Further information that may be of assistance when developing an employer's procedure is available from the Society and College of Radiographers[59] and the Royal College of Paediatrics and Child Health.[56]

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. Schedule 2(i) requires an employer's procedure for providing adequate information on the benefits and risks associated with the exposure and formalises this recognised practice. Information should be given, where practicable, to the individual being exposed, a carer and comforter or the individual's representative prior to the exposure.

For low-dose exposures, posters and leaflets in public areas such as waiting areas or wards may be sufficient. For higher-dose procedures, consideration must be given to how information is provided and by whom and how it is received and understood by patients. There must be an employer's procedure defining how this is achieved prior to seeking consent. Procedures are likely to be different, and the duty holder providing the information may be different, according to dose level and patient pathway.

Schedule 3 includes the requirement for IR(ME)R duty holders to have adequate training on the benefits and risks of radiation and risk communication. It is recognised that communication of the benefits and risks from radiation exposure can be quite challenging. Individuals or their representatives may have difficulty processing information due to an array of emotions, stress, confusion and worry. They may give greater weight to negative information than to positive information being provided. Therefore, it is important to ensure that the benefits of the exposure and the implications of not having the examination are clearly described in a context that the individual can understand.[62] 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 and has been tailored to the individual in keeping with ALARP.

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(s) being exposed to make an informed decision about the exposure being undertaken.

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,[63] 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.

14
Benefits and risks

The employer's procedure should consider providing information in a range of languages to meet local population needs. Within Wales employers must ensure 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.[64,65] Table 14.1 lists examples of different communication methods and things to consider in clinical departments.

Table 14.1: Considerations of different communication methods

Type of communication	Things to consider
Verbal discussion	• Sufficient time and opportunity to have a conversation • Staff training and language used • Use of standard phrases to ensure consistent message and delivered in a way that is understood by the individual • Patient dignity, when choosing the location for discussion • Availability of additional advice (eg MPE)
Poster	• Content of information • Placement and visibility of poster • Size and design of poster • Alternative languages • Invitation to discuss any concerns or request more information
Appointment letter or 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 or cardiology, theatres, CT colonography)

The use of the 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.[66] 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.[67] 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[66]

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

* Lifetime risk of cancer per examination for patients aged 30–60

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Benefits and risks

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 and abbreviations, 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 (eg on the referral form, the RIS, a consent form or the medical notes).

Scenario 17

A pregnant patient arrives in the CT unit from the emergency department with a suspected pulmonary embolism. The referring consultant discusses the patient's condition 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 radiographers explain 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 the radiographer makes a record of the discussions on the RIS.

Table 14.3 includes examples of 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 or unconscious patient	• No information provided to the individual, but it may be discussed with a relative or carer as appropriate
Paediatric patients	• Information provided to parent or guardian • Language used should be relevant to the age of the patient[68,69]
Additional clinical or dose advice is required	• Contact details for support (eg radiologist or MPE)
Patient lacks capacity	• Information provided to representative or to the person with power of attorney for health

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Benefits and risks

Example situations for inclusion in employer's procedure	Things to consider
Patient with sensory impairment	• Consider developing a communication plan that takes into account the unique sensory needs, preferences and abilities of individuals • Ensure staff are trained to understand an individual's preferred methods of communication (eg sign language, braille, tactile communication or other suitable alternatives)
Patients with neurodiversity	• Consider how to support effective communication with neurodivergent individuals
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 the Ionising Radiations Regulations 2017 (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:

- Be provided before the patient leaves the hospital
- 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
- 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.

Regulation 12(6) describes who this information should be given to and considers situations where the patient is a person aged 16 or older who lacks capacity or competence to consent. The 2024 amendment acknowledges the term capacity is applied in Scotland and the term competence is applied in England and Wales to a child under the age of 16. Where the patient does not have capacity or competence to consent, the written instructions should be provided to the person who appears to the operator to be the most appropriate person.

15 Children and young people

Children, teenagers and young people are often considered together as a distinct group of patients in healthcare guidance.[70] Different services may have different age categories at an operational or service level.

Regulation 12(8)(a) says that the practitioner and operator must pay particular attention to the optimisation of exposures performed on children. 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.

Children are at greater risk of radiation-induced injury than adults due to their rapidly growing and dividing cells and longer expected lifespan. The benefits of a diagnostic investigation involving ionising radiation should be considered in conjunction with the increased risk to the child. Schedule 3 requires practitioners and operators to be adequately trained in the management and radiation protection of infants and children, as relevant to their functions.

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.

Consideration should also be given to alternative techniques that do not use ionising radiation, in order to answer the clinical question. Specific medical conditions in childhood are not necessarily investigated and managed in the same way as for adults, so alternative techniques and modalities must be considered.

Some examples are:

- The investigation of developmental dysplasia of the hip (DDH), which is better visualised with ultrasound, as developing tissues are less visible on plain film images.
- Imaging of the chest for suspected infection, as there are fewer indications for imaging in children due to the different course and pattern of risk for the child with chest infections.

When considering referrals for paediatric imaging, the justification process and protocols used for adults may not necessarily be appropriate. Paediatric referral guidelines are available.[28]

Where a practitioner issues authorisation guidelines, they should include specific paediatric criteria to enable operators to authorise these referrals. Authorisation guidelines should clearly define the paediatric cohort, such as age range.

Imaging children poses distinct challenges.[69] 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.

15 Children and young people

Regulation 12(8)(a) requires the practitioner and operator to pay particular attention to the optimisation of exposures of children. This can be supported by considering inclusion of child-friendly aspects of the exposure process. For example, the room should be equipped with the necessary accessory equipment such as positioning aides 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 an appropriate range of dose reduction features and, where possible, a broad selection of pre-programmed exposure factors based on a range of ages or weights.[42] 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 international paediatric DRLs should be made available to staff.[39,40]

In childhood, the likelihood of practical difficulties such as anxiety, fear, lack of co-operation and inability to remain in position is much greater. Experience and expertise are required when imaging children and young people. Gaining the trust and co-operation of the child, with clear age-appropriate communication between the operator and both the child and parent or guardian, will improve the probability of getting successful and adequate diagnostic images first time.[69]

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)	• Optimising administered activity • Effective and appropriate immobilisation techniques • Collimation (rather than post-process image cropping) • Appropriate use and selection of grids, focal spot, AEC etc • Pre-programmed exposure factors on all equipment • Use and development of paediatric exposure or administered activity charts (age, weight or 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 or phases; for example, a single anteroposterior (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.

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Children and young people

Professional bodies and employers should continue to provide opportunities for staff to undertake CPD and specialist training in paediatric imaging.

Care should be given to the appropriate use of high-dose examinations for children such as CT or PET-CT, with a multidisciplinary approach to optimisation through groups such as multidisciplinary optimisation teams.[71]

It is important to liaise with parents or guardians in advance of the exposure to provide information and understand the child's needs and requirements. To support patient experience, there should be consideration of additional requirements such as advice about sedation, cannulation procedures to minimise pain, involvement of play specialists and whether there are appropriate facilities for this locally.[69]

Specific 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 EANM.[18,72,73]

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 (eg residential care home assistants or Macmillan nurses) should be considered under IRR2017.[74]

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 when providing psychological, emotional or physical support. The procedure should include relevant dose constraints and outline the steps to be taken by IR(ME)R duty holders to identify such individuals.

The employer must establish dose constraints for carers and comforters [Regulation 6(5)(d)(ii)]. The employer's procedure should allow flexibility when establishing appropriate dose constraints to encompass the variety of circumstances involving exposure to carers and comforters. The advice of the MPE should be sought when setting appropriate dose constraints. Different dose constraints can be set for each modality. Departments may find a dose constraint per episode easier to record and monitor than an annual dose constraint.

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.[75] 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 (eg 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.

16 Carers and comforters

Table 16.1: Suggested criteria for carers and comforters

Criteria	Examples
Individuals who provide support and comfort to a patient within a controlled or supervised area (where access is normally restricted, or systems of work are in place to exclude members of the public) Schedule 2(n)	During an exposure: • Being with a patient in an examination 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
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), 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 is informed of the risks and agrees to the exposure, this may be justified by the practitioner.
- Children who act in a caring role would not normally be designated as carers and comforters. Trust or 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.[76]

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.

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Carers and comforters

Scenario 18

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 (issued by a practitioner), as described in Chapter 7. This might not be the person who initially justifies and authorises the exposure to the patient. A practitioner justifying exposures to carers and comforters does not need to hold a practitioner licence as required under Regulation 5(1)(b). The practitioner must be a registered healthcare professional and must be appropriately trained and entitled.

Specific matters that must be considered by the practitioner when justifying any exposure (to the individual or to the carer and comforter) are outlined in Table 7.1 [Regulation 11(2)]. Additional considerations must be applied to the justification of exposures to carers or comforters as detailed in Table 16.2 [Regulation 11(3)(b)]. Where authorisation guidelines for carers and comforters are issued, the additional requirements of Regulation 11(3)(b) should be included.

Table 16.2: 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 someone they trust with them during a diagnosis or treatment
(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?

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

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Carers and comforters

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. 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 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 and 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 16.3 summarises the requirements for carers and comforters and associated matters to consider.

Table 16.3: 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 and records • Involvement of the MPE in setting dose constraints
Entitlement Schedule 2 (b)	• Identifying appropriate individuals entitled to act as practitioner for justification of exposure to carers and comforters or operators authorising under authorisation guidelines
Individual justification Regulation 11(1)(b)	• Benefits and risks from the exposure to the carer and comforter • Criteria for individual justification by practitioner
Communicating benefits and risks Schedule 2(i)	• Information leaflets and posters for carers and comforters • Non-standard situations where additional written information for carers and comforters is required • Appropriately trained staff to answer any questions the carer or comforter may ask during consent
Establishing dose constraints Regulation 6(5)(d)(ii)	• Dose constraints for standard scenarios and risk assessments • Flexibility to set appropriate dose constraints that cover non-standard circumstances, where an individual risk assessment is required • Involvement of the MPE
Guidance Regulation 12(5)	• Practical information to keep exposure below the dose constraint • Involvement of the MPE

17 Health screening and individual health assessment

Regulation 3(1)(b) applies to those invited to participate in health screening programmes. These individuals 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.

Regulation 3(1)(e) applies to the exposure of asymptomatic individuals outside of national health screening programmes. This includes IHAs that are used for those asymptomatic individuals who, based on their own personal circumstances, may wish to seek reassurance by excluding unknown underlying disease.

National screening programmes

The UK National Screening Committee (UK NSC) advises ministers in the four UK countries about national screening programmes. Its 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. It does this by using strictly defined criteria and review processes.[77]

National screening programmes are proactive, evidence-based, planned, resourced and nationally co-ordinated. National screening programmes select participants from a population who may be considered at risk of a particular condition or disease. Those selected receive an invitation to attend for a diagnostic test rather than seeking an individual referral from a healthcare professional. As the referral process differs, consideration should be given to who is acting as the referrer and how the referral is evidenced.

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.[36] National screening programmes must follow all the requirements for IR(ME)R, including referral, justification, optimisation, training and clinical evaluation. 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), 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 screening programme should only be provided locally if the planned screening pathway and the potential benefits and risks of screening have a clear evidence-base.[78]

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Screening and assessment

Individual health assessment

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.

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 clinical evaluation, in the same way as any other medical or non-medical exposures.

Scenario 19

A healthy 32-year-old woman has volunteered to donate a kidney to her 58-year-old father, who has end-stage renal disease caused by long-standing hypertension. To ensure that the donor has adequate renal reserve to safely donate, the transplant nephrologist requests a nuclear medicine GFR study. This test will provide a precise measurement of her GFR and help determine whether her remaining kidney would be sufficient after donation. The results of the nuclear medicine study will be reviewed by the transplant committee before final approval for surgery.

In scenario 19, the exposure is not for the donor's own medical diagnosis or treatment and so is classed as an IHA for the purposes of IR(ME)R.

Scenario 20

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.

Justification of exposures for asymptomatic individuals

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.

Exposures for health screening programmes and IHA of asymptomatic individuals must be justified, optimised and clinically evaluated in the same way as for other medical and non-medical exposures. Justification for an IHA may consider risk factors rather than symptoms.

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

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 or emigration purposes (visa application process)
- Assessment for insurance purposes (medico-legal claims)
- Identification of concealed objects within the body (drug smuggling).[79]

NMI exposures that use non-medical equipment, such as security screening at airports and ports, are outside the remit of 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. The employer's procedure should detail the specific types of NMI provided in the organisation.

NMI exposures using medical radiological equipment must follow the IR(ME)R framework, which requires entitled duty holders to refer, justify, authorise and clinically evaluate the exposure. 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 and clinical history should be considered as part of the justification process.

Regulation 6(5)(c)(iii) states that DRLs should be established for NMI exposures where practicable, with reference to local dose surveys.

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 (eg using a specific code on the RIS).

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

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NMI exposures

Table 18.1: 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	• Divers, oil rig workers or heavy goods vehicle drivers requiring physical assessments for certain aspects of their roles
Immigration or emigration Many countries require individuals to undergo chest radiography as part of the visa application process	• Tuberculosis screening
Insurance Previously known as medico-legal exposures	• Exposures to support court action
Identification of concealed objects within the body The individual does 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

Scenario 21

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, indicating the NMI status, 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. A clinical evaluation of the exposure is documented within the individual's record.

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

An MPE must have 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).

MPEs are required to demonstrate competence and gain certification through a designated system; further details on this process can be found on the RPA2000 website.[80]

Regulation 14 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 with a defined scope of practice in accordance with the employer's procedure.

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.[81]

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

Type of practice	Level of involvement		
	Closely involved	Involved	Involved as appropriate
Radiotherapeutic practices			
Standardised therapeutic nuclear medicine practices			
Diagnostic nuclear medicine 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. An MPE for a service providing only low-dose exposures (eg general radiography in a community hospital or low-dose nuclear medicine exposures in a research lab) could be off site. An MPE for high-risk or non-standard nuclear medicine therapy services should be readily available at the site. The MPE should have a greater level of involvement in high-dose diagnostic radiology, such as interventional radiology, cardiology and high-dose CT. Medical physics service 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.

19 Role of MPE

The MPE should have an understanding of the local service and level of support required for the sites where they are entitled. 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, as detailed in Regulation 14, are covered and that work is not duplicated. Further guidance is available for MPE support levels for nuclear medicine services.[81]

Table 19.2: Examples of the roles of an MPE

Area	Role examples
Equipment procurement and commissioning	• Advice and input on equipment selection including equipment outside radiology or nuclear medicine • Preparation of technical specifications and installation design
Equipment management	• Acceptance testing • Definition and establishment of QA programme • Provision of advice following QC • Undertaking in-depth QC • Update and management of equipment inventory • Managing equipment faults
Optimisation	• Protocol development • Introduction of new and developing techniques • Use of technological features and reconstruction or image presentation • High-dose examinations on individuals requiring special consideration prior to the exposure (eg pregnant individuals)
Dosimetry	• Dose audits • Establishment of LDRLs • Radiation incident analysis including dosimetry calculations and preventative action(s) • Establishment of dose constraints, where required • Investigation and dose assessment following high-dose procedures (eg skin dose calculations following long and complex interventional or cardiac procedures)
Regulatory compliance	• Input to employer's procedures and policies • Compliance audits and level of MPE involvement • Provision of advice on compliance to the employer • Contribution and participation in RPC meetings
Training	• Local user QC • Radiation protection (aspects of IR(ME)R) training for all staff using equipment • Update training for existing staff

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Role of MPE

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 liaising with practitioners and operators 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 or oversee a critical examination on newly installed equipment. The MPE is also required 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 all required. For example, for the introduction of a sentinel node service in a theatre where gamma probe QC is required (MPE), local rules need to be written (RPA) and waste protocols developed for theatres (RWA).

20 Equipment and quality assurance

Regulation 15 sets out the requirements for employers in relation to all equipment regardless of location or 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 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 programme is working as it should, such as audit.

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.

Definition of equipment under IR(ME)R

Within IR(ME)R 'equipment' is defined [Regulation 2] as equipment (including software) that:

- 'delivers' ionising radiation to a person undergoing an exposure; or
- 'directly controls or influences' the extent of the exposure and hence the dose delivered; or
- 'directly assists' an operator in carrying out a clinical evaluation.

The definition of equipment now includes software that directly assists an operator in carrying out a clinical evaluation. This software cannot be used autonomously and the operator using the software is responsible for the clinical evaluation. Examples of equipment and software are listed in Table 20.1.

Table 20.1: Examples of equipment and software

Type of equipment	Examples
Equipment delivering ionising radiation	• X-ray tube • CT scanner • DXA scanner • Image intensifier • Fluoroscopy unit • PET-CT scanner
Ancillary equipment (including software) that influences the exposure	• CT contrast injector pump • Equipment used for gated examinations (eg electrocardiogram leads) • Gamma cameras • Gamma probes • Radionuclide dose calibrators • Software used for 3D patient positioning

Type of equipment	Examples
Ancillary equipment (including software) that directly assists with clinical evaluation	• Software that highlights abnormal or potential abnormal findings in a study • Software that assists with segmentation and contouring (eg PET-CT)

Equipment used to facilitate or support clinical evaluation (eg 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. Software that is part of the equipment itself or is used to support image processing prior to clinical evaluation does not need to be included in the inventory. For example, image processing tools on PACS might be used to prepare an image prior to clinical evaluation. Voice recognition software used to generate clinical reports does not need to be included on the inventory.

Equipment and the employer's responsibilities

Regulation 15 defines the general duties of the employer with respect to equipment. These are summarised in Table 20.2 and discussed in more detail below.

Table 20.2: Employer's duties regarding equipment

Employer's duty	Things to consider
Implement and maintain an equipment QA programme. Regulation 15(1)(a)	Arrangements for equipment QA programme including: • Types of tests • Frequency of testing • Training of operators to perform tests • MPE involvement
Keep an up-to-date inventory of equipment (including relevant software) Regulation 15(1)(b)	• Include software and all ancillary equipment that can directly influence the exposure or assist with clinical evaluation • Remove equipment no longer in use • Include equipment located outside of the department (eg mini C-arms and gamma probes)
Carry out testing of equipment prior to use for any medical purpose Regulation 15(3)(a)	• Programme for acceptance testing • Programme for routine QC testing
Carry out regular performance testing Regulation 15(3)(b)	• Agreed programme for QC testing • Daily, weekly, monthly, quarterly or annual medical physics testing
Carry out testing following any maintenance that may affect the equipment's performance Regulation 15(3)(c)	• Handover arrangements and lines of accountability for on-site and remote maintenance • Procedure for informing of and co-ordinating testing with medical physics team • Procedure for notifying operators of any relevant changes when equipment returns to normal use

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Equipment and QA

Employer's duty	Things to consider
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), 15(6)(c)	• Record QC results • Define baselines, tolerance and action levels • Procedure to take equipment out of service • MPE involvement • Risk register • Image optimisation team (IOT), or equivalent
Equipment must have a device capable of automatically controlling the radiation dose rate, such as an image intensifier Regulation 15(4)	• MPE involvement in specification for any high-dose 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

Where equipment is shared by multiple employers (eg NHS-owned intraoperative gamma probes may be used in private healthcare settings), clear procedures on the responsibilities of each employer should be established to ensure all duties in Table 20.2 are covered. Further advice on co-operation between employers is included in Chapter 2.

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

Table 20.3: Requirements under Regulation 16

Regulation	Requirement
Real-time exposure monitoring Regulation 16(3)	• All interventional radiology equipment must have a means of informing those performing the examination of the amount of radiation produced during that exposure
Parameters for assessing patient dose Regulation 16(6)(a)	• All equipment that produces ionising radiation must be able to inform the operator of parameters required for assessment of patient dose, such as an indication of DAP or DLP
Exposure record Regulation 16(5) and Regulation 16(6)(b)	• All interventional radiology and CT equipment must be able to transfer dose information to a person's exposure record • Where appropriate, other equipment must have the capability to transfer dose information to the person's exposure record

A multidisciplinary team approach to equipment management is essential. Table 20.4 describes things to consider throughout the life cycle of medical radiological equipment.

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Table 20.4: Matters to consider throughout the equipment life cycle

Stage in the equipment life cycle	Things to consider
Selection of equipment	• MPE involvement [Regulation 14(3)(d)] • Choice of the most appropriate equipment to meet the service requirements • Procurement phase of equipment selection • Assessment of dose optimisation features on tendered equipment
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 • Clear line of responsibility for equipment located outside of radiology
QA programme	• Testing equipment performance at specified intervals and after major maintenance or software updates [Regulation 15(3)(b)] • 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	Employer's procedures for accepting equipment back into clinical use following: • Service or maintenance [Regulation 15(3)(c)] • On-site or remote software updates
Inadequate or defective equipment	• Regular assessment of equipment • Doses from medical exposures being significantly greater than LDRLs or NDRLs or degradation of image quality • Equipment breakdown • Equipment that does not meet the current clinical requirements • Escalation process for dealing with inadequate or defective equipment [Regulations 15(6)(a) and (c)] • Procedure for taking equipment out of service or decommissioning equipment

The requirements in Table 20.4 may also apply to software in use within clinical departments, as described in the following scenario.

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Equipment and QA

Scenario 22

A radiology department has decided to implement AI software to support operators with clinical evaluation.

For this software, the intended use is to support fracture identification on appendicular radiographs. The intended use, functionality, limitations and potential risks are documented.

The performance metrics are determined. The software is first piloted using a non-clinical setting such as 'shadow mode'. On completion of the pilot and acceptance testing, the software is added to the software inventory.

Operators performing clinical evaluation in the emergency department are identified as the group of operators who will be using the software. This staff group are provided with training for the software, which is evidenced in the local staff training records. Once competence is assessed and confirmed, this is added to the operator's individual scope of practice.

An audit process is set up for continuous performance monitoring. A radiologist is assigned to oversee the software use and outputs.

Equipment QA programme

Regulation 15(1)(a) and Schedule 2(d) require the employer to have employer's procedures in place to ensure that the equipment QA programme 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 on who will be responsible for specific tests.[82] The advice of an MPE should be sought when reviewing results of QC testing that drift or fall out of tolerance. More detail can be found on the involvement of the MPE in QA programmes in Chapter 19.

Information and guidance on ionising radiation equipment QA and QC testing can be found in the report series published by IPEM.[83]

The operator has a specific responsibility to consider QA and QC when ensuring that exposures are ALARP [Regulation 12(3)(a)]. Table 20.5 provides examples of what should be considered for inclusion in an equipment QA programme.

Table 20.5: 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 changes to hardware or updates to software
Who will test?	• Trained and entitled staff (eg daily or monthly QC tests, after engineer visit) • Medical physics

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Equipment and QA

QA programme	Things to consider
Prior to external testing (eg faults, servicing)	• Equipment handover (eg the Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (AXREM) form)[84] • Equipment or software handover for remote maintenance • Examine equipment log for known issues and previous engineers' reports
During testing	• Specific tests for each equipment type • Appropriate testing resources • How to set up specific tests, including distances, exposure parameters and position of phantoms • Recording results • Ensure tolerances available • Record of assessment of results against tolerances
After testing	• Report any issues in accordance with local procedures • 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)[84]
Review and improvement	• Review results to demonstrate performance over time • Record of faults and corrective actions • Training and competency records of those performing QC

Equipment handover

Robust procedures for handover of equipment should be established between external service engineers and local MPEs or radiography and technologist staff. In cases of remote maintenance where adjustments to software could influence radiation safety, patient dose or image quality, there should be a formal process for testing and accepting equipment back into clinical use.

External service engineers would not normally be considered operators. For further information on duty holders' roles and responsibilities see Chapter 2.

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.

The inventory must also include software that can assist with clinical evaluation. Software that is part of the equipment itself or used to support image processing prior to clinical evaluation does not need to be included in an inventory under this definition (eg iterative reconstruction).

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Equipment and QA

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.

For software, the inventory must include:

- Name of the software company
- Brand name
- Current software version
- Year of original installation
- Year of current software version installation in clinical use.

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.

21 Accidental or unintended exposures

Accidental or unintended exposures

Regulation 2 defines the terms 'accidental exposure' and 'unintended exposure'. The Regulations require the employer to provide a system for analysis, recording, reporting and ensuring appropriate action is taken, in relation to accidental or unintended exposures [Regulation 8(3)]. The MPE must contribute to this incident analysis system by assessing the potential dose and risk involved [Regulation 14(3)(f)].

The Regulations differentiate between significant accidental or unintended exposures (SAUE) and clinically significant accidental or unintended exposures (CSAUE).

Significant accidental or unintended exposures (SAUE)

These exposures are significantly greater than intended. The Regulations require that SAUE are notified to the relevant enforcing authorities.[61] Employers must ensure they have access to the most recent version of the SAUE guidance.

Clinically significant accidental or unintended exposures (CSAUE)

These accidental or unintended exposures have a clinically significant impact on the individual exposed. The SAUE guidance requires that CSAUE are notified to the relevant enforcing authorities. Regulation 8(1) requires the referrer, practitioner and individual exposed or their representative to be informed of a CSAUE.

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.[85] The definition of moderate harm required to trigger the duty of candour has been used as the basis for the following guidance. The Learn from Patient Safety Events (LFPSE) service defines events that cause moderate harm giving consideration to physical or psychological harm.[86]

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 CSAUE definitions presented in Table 21.1 and the LFPSE guidance should be considered by the multidisciplinary team when investigating an incident.

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SAUE and CSAUE

Table 21.1: CSAUE definitions

Tissue effects	Definition
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 • A CSAUE is defined for fetal exposures where the pregnancy was not known about as an accidental or unintended exposure to ionising radiation that results in a 0.1% (1 in 1,000) or greater risk of radiation-induced childhood cancer
Deterministic tissue injuries	A CSAUE is defined as an unjustified exposure to ionising radiation greater than: • 0.5 Gy to the lens of the eye[87] • 0.5 Gy to the heart or brain[87] • 5 Gy dose to skin (including backscatter) causing skin reactions (eg erythema for more than two weeks, more severe skin reactions and permanent partial epilation);[88] extravasation of some radiopharmaceuticals may result in skin doses greater than 5 Gy • 50 mGy to the thyroid following the administration of a radiopharmaceutical where there has been a failure in the thyroid blocking procedure

Dose and risk calculation

The dose and risk calculation should only assess the risk from the additional accidental or unintended exposure. Dose and risk estimates for potential CSAUE should be calculated by an MPE using age- and sex-appropriate cancer risk factors.[89] For individuals with a reduced life expectancy, such as a patient on a palliative care pathway, consideration should be given to adjusting the lifetime radiation-induced cancer risk. The MPE assessment of stochastic risks may contribute to the multidisciplinary decision to classify an incident as CSAUE despite the thresholds for SAUE under Regulation 8(4) of IR(ME)R not being met.

Scenario 23

A two-day-old female paediatric patient on the neonatal ward required a mobile abdominal X-ray. The radiographer carrying out the examination failed to notice the mobile unit had defaulted to an adult setting. The radiographer on reviewing the image on the mobile unit noticed the image was undiagnostic. The radiographer repeated the image, again using the same adult setting.

The incident was reported on the local incident management system and the MPE was asked to calculate dose delivered and estimate the lifetime cancer risk to the child from the additional unintended exposure.

An approximate 1 in 870 chance of a radiation-induced cancer risk was calculated by the MPE and presented to the paediatric radiologist, who determined that this incident was a CSAUE as the criteria for moderate harm had been met. The patient's parents and referring doctor were informed of the outcome of the investigation.

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SAUE and CSAUE

Scenario 24

A patient was administered with 18F-PSMA, but extravasation occurred with the majority of the intended administered activity tissuing in the patient's arm. The subsequent investigation by the MPE calculated that the dose to the skin was 5 Gy. This is a CSAUE as the threshold for deterministic effect was reached.

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. For example, an interventional procedure where the practitioner continues to expose the patient past the dose threshold (alarm) recognising that skin erythema will occur but having made the clinical decision to continue with the procedure 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 LFPSE 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. 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.

Communicating CSAUE occurrence

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.

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, for example, age, mental health and the magnitude of the exposure.

When individuals are informed of an event and an explanation of the risks is given, it is advisable to consider risks in broad categories.[89,90] Employers may need to consider appropriate investigation training of duty holders, and it may be helpful to develop supporting documents to aid this process. Further details on communicating risk information can be found in Chapter 14.

Incident investigation process

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[61]
- Carry out a detailed investigation including assessing the potential dose received
- Notify the relevant enforcing authority of the outcome and corrective actions.

The process of investigation should be standardised where possible. Lessons learned from an investigation can be applied to prevent an event from occurring in the future.

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SAUE and CSAUE

Table 21.2 includes things to consider for inclusion in a comprehensive incident investigation procedure.

Table 21.2: Procedure for local incident reporting, investigation and external notification

Area	Things to consider
Preliminary investigation process	• Immediate action to ensure the safety of the patient(s) • Action to ensure the event is not repeated (eg equipment taken out of service) • 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 • Identify those responsible for managing the internal escalation process (eg the radiation protection supervisor or senior site lead) • Involvement of the MPE (eg estimation of overexposure) • External notification thresholds and timescales (eg SAUE guidance,[61] CSAUE definition) • Identify responsible person for notifying the relevant enforcing authority (where required)
Detailed investigation process	• Identify 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 • Report on what happened and compare with what should have happened
Clinically significant accidental or unintended exposures	• Involvement of the MPE to estimate dose delivered and risk to individual exposed • Multidisciplinary decision on whether accidental or unintended exposure is clinically significant • Informing the individual exposed or their representative, the referrer and practitioner
Informing the individual exposed or 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[49,91] • Systematic analysis of events, as part of a just 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 • Taking action on lessons learned in the analysis of the event to prevent repeat incidents

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SAUE and CSAUE

Regulatory notifications

Guidance is available from the enforcing authorities on situations where radiation incidents should be notified to them, along with appropriate timescales for notification.[61] Notifications to the relevant enforcing authority should include contact details of an individual who can provide further information as required. Notifications should not include information that could identify the patient or staff involved.

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

- In England, the enforcing authority is the 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 for 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, Wales and Northern Ireland, and Health Facilities Scotland in Scotland.

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.[92]

System for recording analyses of events

Regulation 8(3) requires the employer to put in place systems for recording analyses of events and taking appropriate actions in relation to such analyses.

Most incidents or near misses are not just a series of random, unconnected events. Events may arise from multiple, interacting components of a system. The investigation should therefore adopt a system-based approach and ensure all contributory factors are identified and appropriate action is taken. Although each event is unique, there are likely to be similarities and patterns that may go unnoticed if events are not reported and analysed. The national coding taxonomy and supporting guidance is available to standardise the classification of incidents and near-miss events in diagnostic imaging and nuclear medicine.[91]

Documentation relating to incidents and near misses should be retained in line with relevant guidance.[93] Clinical departments should keep records of incidents and near misses. These should be made available to all staff to facilitate learning and support safer working.

Employers should share the outcomes of analyses with all relevant staff and apply lessons learned to mitigate these events in future.

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SAUE and CSAUE

Reducing the probability and magnitude of accidental or unintended exposures

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

Table 21.3: Employer's procedure to reduce the probability and magnitude of accidental or unintended exposures

Area	Things to consider
Governance	• Establishment of RPCs, or similar • Clear arrangements for co-operation between employers
Optimisation	• Modality-specific training • Use of dose audits • Peer review of images to assess image quality, positioning, collimation and so on • IOT or similar group or committee • MPE involvement
Communication	• Effective communication with the patient to facilitate co-operation during the examination or procedure • Understanding of the importance of different communication styles for different patient cohorts (eg paediatrics, learning difficulties, non-English speakers) • Culture of multidisciplinary team working • Sharing of learning from audits and incidents • Communication with safety and governance committees
Audit	• Participation in audit programme • Audit of appropriateness of referrals and justification • Audit of all parts of the clinical pathway • Monitoring of compliance with employer's procedures
QA programmes	• Robust QA programme for documentation and equipment • Regular QC testing of 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 • Ongoing CPD and refresher training as required
Entitlement	• Effective entitlement process with up-to-date scope of practice for individual duty holders including duty holders external to the imaging or nuclear medicine department
Incident and near miss analysis	• Analysis of trends to identify any need for change in practice or procedure or a need for further training • Undertaking appropriate and robust action in relation to the analysis of trends • Shared learning locally, regionally or nationally

22 Nuclear medicine licensing

Regulation 5(1) requires employers and practitioners who administer radioactive substances to hold a valid licence. Each employer licence is specific to the site where administrations will take place and lists the authorised procedures (examinations) that may be carried out for diagnostic, therapeutic and research purposes. Each practitioner licence lists the authorised procedures that may be justified by the named licence holder for diagnostic, therapeutic and research purposes.

Applications for licences are assessed by ARSAC and issued by the appropriate licensing authority.[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.

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Nuclear medicine licensing

In order to carry out a procedure (examination), the relevant procedure code must be included on both the employer and practitioner licences for the same purpose.

Scenario 25

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 or 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.[18]

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.

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.[18]

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.[95]

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.

Regulation 240 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 the requirements and things to consider when carrying out research.

Table 23.1: List of requirements under the Regulations for research

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

The employer is also required to have in place an employer's procedure regarding exposures involving ionising radiation for research purposes [Schedule 2(g)]. Table 23.2 includes considerations for inclusion in this employer's procedure and gives some examples of how the written procedure could describe how they may be addressed in practice.

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Research

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
Individuals participate voluntarily	• Clear description of the research consent process, including consent for radiation exposure(s) • 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)[96]
Dose constraints	• Description of how a dose constraint is set for each research trial and how centrally reviewed data are used to inform local dose constraints • Local dose constraints should be optimised and reasonable variations in local practice (eg available equipment) taken into consideration • Process to ensure dose constraints are adhered to
Dose targets	• Description of how individual dose target levels are set • Description of how delivered doses are recorded and monitored

Central review and approval for research

The HRA has produced guidance to aid research trial sponsors in determining if the exposures within a trial are research exposures.[97] ARSAC has produced guidance to describe when ARSAC research approval must be obtained.[94] Ethics committee and ARSAC approval are two separate activities and this approval does not automatically mean that all the research exposures included in the study have been justified and authorised on an individual level.

Ethics committee approval

Before any research involving exposures to ionising radiation can go ahead, the research trial must be approved by a REC. This ensures the ethical merit of the trial has been evaluated by a group of individuals with the appropriate knowledge and skills. Further detailed guidance is available from the HRA on how to apply for REC approval.[97]

23
Research

ARSAC approval

Research involving the administration of sealed or unsealed radioactive substances will require approval from ARSAC. Research sponsors are responsible for obtaining ARSAC research approval. Detailed information on this process can be found on the ARSAC website.[94]

ARSAC research approvals will specify the radiopharmaceutical and its use.

Considerations for research trial initiation at site

A local governance and oversight process is required so that the employer can assure itself that it can meet the requirements of IR(ME)R for research. This should include a proportionate review of the research trial requirements to ensure that the site can safely deliver the associated exposures.

Licensing for the administration of radioactive substances

Appropriate employer and practitioner licences are required prior to commencing a research study involving the administration of radioactive substances. The procedure codes approved for the study need to be held on both the employer and practitioner licences for the purposes of research. If these procedures are not held, the licences should be amended appropriately following ARSAC guidance.[18]

Referral

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

Justification

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

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

23
Research

Practical considerations

IR(ME)R requires employer's procedures to provide safeguards for medical and biomedical research trials. It is important that local departmental staff can identify those exposures that are for research purposes. This can be achieved in several ways, such as by selecting a 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 the local department.

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

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

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

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

Scenario 26

A research study that is approved by ARSAC, REC and HRA involves the use of 18FDG PET/CT scans.

The local employer's procedure for research includes the need for an assessment of the site's capability to take part in the study. This involves members from a multidisciplinary team.

- The R&D department confirm that REC and HRA approval is in place and share the ARSAC approval with the nuclear medicine department.
- The REC-approved PIS is supplied and used locally to support the consent process.
- The MPE completes a local dose assessment and sets a local dose constraint in line with the central review.
- The service manager checks the employer and practitioner licences are in place.
- The practitioner licence holder checks the imaging protocol meets the trial requirements in the imaging manual.

A research folder is established and made available to staff on the local network and the trial can begin.

A1 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 intellectual process of justification has occurred. Evidenced either by written or electronic signatures.
Carer and comforter	An 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 interpretation of the outcome and implications of the information resulting from a medical exposure by an appropriately trained and competent operator.
Clinically significant accidental or unintended exposure	An accidental or unintended exposure that has 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 intentional maintenance or development of knowledge, experience, skills or 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	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	The process of verifying and documenting that the duty holder has the necessary training and competencies to undertake the task as defined in their scope of practice.
Equipment life cycle	The overall lifespan or process of a physical asset, from planning and procurement to disposal or renewal.
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 (eg when the error is detected before the individual is exposed).
Event	Something that happens to or involves a patient.

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Appendix 1

Term	Definition
External notification	The required process of informing the relevant regulatory body about a significant event.
Justification	The 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 or 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, including clinical evaluation where indicated.
Optimisation	The process by which individual doses are kept as low as reasonably practicable (ALARP).
Policy	A high-level statement governing the conduct of activities in an organisation. Policies outline what will be done, with minimal detail on how this will be achieved.
Population dose	A collective dose measurement that represents the overall radiation exposure received by a group of people used to assess overall radiation impact.
Positive patient identification	The process of correctly identifying a patient by actively seeking the patient's verbal or written response to a set of core identifiers.
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	A written standardised step-by-step description of how an examination is carried out. It 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 QA.

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Appendix 1

Term	Definition
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 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	A person or body with the legal jurisdiction to ensure compliance with specific regulations within a particular area or for a given activity; in this case pertaining to the exposure to ionising radiation within a healthcare setting. 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
Scope of practice	A range of skills and tasks, based on professional registration, education, training, knowledge and experience, that an individual is competent to perform.
Significant accidental or unintended exposure	An exposure to radiation that was significantly greater than that intended. The Regulations require that SAUE are notified to the relevant enforcing authorities.
Supervision	The action or process of watching and directing what someone does or how something is done and being in a position to change this when required.

A2 Abbreviations used in this document

Abbreviation	Definition
AI	Artificial intelligence
ALARP	As low as reasonably practicable
ARSAC	Administration of Radioactive Substances Advisory Committee
AXREM	Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care
BNMS	British Nuclear Medicine Society
CPD	Continuing professional development
CQC	Care Quality Commission
CR	Computed radiography
CSAUE	Clinically significant accidental or unintended exposure
CT	Computed tomography
DAP	Dose area product
DHSC	Department of Health and Social Care
DLP	Dose length product
DR	Digital radiography
DRL	Diagnostic reference levels
DXA	Dual energy X-ray absorptiometry
EANM	European Association of Nuclear Medicine
FRCR	Fellowship of The Royal College of Radiologists
GDPR	General Data Protection Regulation
GFR	Glomerular filtration rate
HCPC	Health and Care Professions Council
HIS	Healthcare Improvement Scotland
HIW	Healthcare Inspectorate Wales
HRA	Health Research Authority
IHA	Independent health assessment
IOT	Image optimisation team
IPEM	Institute of Physics and Engineering in Medicine
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
LDRL	Local diagnostic reference level
LFPSE	Learn From Patient Safety Events
MPE	Medical physics expert
NDRL	National diagnostic reference level
NMI	Non-medical imaging
NMR	Non-medical referrer
PACS	Picture archiving and communications system
PET-CT	Positron emission tomography computed tomography

A2

Appendix 2

Abbreviation	Definition
PIS	Participant information sheet
POM	Prescription-only medicines
QA	Quality assurance
QC	Quality control
QMS	Quality management system
RCR	The Royal College of Radiologists
REC	Research ethics committee
RIS	Radiology information system
RPA	Radiation protection adviser
RPC	Radiation protection committee
RWA	Radioactive waste adviser
SAUE	Significant accidental or unintended exposure
SoR	Society of Radiographers
SPECT	Single photon emission computed tomography
UKHSA	UK Health Security Agency

A3 Key things to consider for co-operation between employers

IR(ME)R employers must co-operate with each other to ensure the requirements of IR(ME)R are being met. The following table includes areas for consideration to enable the co-ordination of services to minimise risks and ensure patient safety.

Table A.3.1: Considerations for co-ordination between employers

Requirement	Things to consider
Type of service	What type of service is being agreed? For example: • Outsourcing of specialist services, or specific areas of a service, such as clinical evaluation or MPE support • Insourcing of services, such as a third-party organisation providing a particular service on trust or health board premises or equipment
Agreed documentation	Is the detail of the agreement between employers recorded? For example: • Service-level agreement • Contract
Governance and employer's responsibilities	Are there clear governance arrangements in place to demonstrate accountability along the patient pathway? For example: • Is there a clear structure to show IR(ME)R governance? • Is there an organisation chart to show chain of accountability? • How are training records shared and maintained? • How are the IR(ME)R duty holder roles and responsibilities outlined at each part of the exposure pathway? • Can you identify which employer's procedures, policies and written protocols staff are working to for each part of the patient pathway? • Can you demonstrate how staff access and share relevant documents and patient records, where required? • Does the IR(ME)R employer responsible for administering radioactive substances hold a valid licence at the site? • Can each of the employers demonstrate IR(ME)R compliance through audit?
Referrals	What arrangements are in place for referrals? For example: • What referral criteria will referrers use? • How will they be given access to them? • How are referrals managed? • Do all referrers have access to the procedure for making, amending and cancelling referrals?
Justification and authorisation of referrals	How are the roles of the practitioners identified? For example: • Who will justify* and authorise referrals? • If authorisation guidelines are used, who will issue them?** • Who will be responsible for choosing the imaging protocol and how is this evidenced? • What is in place if a referral needs to be discussed or amended?

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Appendix 3

Requirement	Things to consider
Justification and authorisation of referrals	What processes are in place where examinations are outsourced? For example: • When does justification and authorisation occur? Is this prior to or after transfer of the referral to another imaging service? • If justification and protocol selection are determined prior to transferring the referral to another imaging service, is this information clearly available to the operator performing the examination? * For exposures involving the administration of radioactive substances, consideration must be given as to who will ensure the practitioner is appropriately licensed. **Consideration must be given to ensure entitlement of the appropriate practitioner where authorisation guidelines are issued.
Practical aspects	What arrangements are in place for operators to carry out practical aspects of the exposures? For example: • Is there a process in place to deal with discrepancies with patient demographics or clinical information? • How will operators check previous clinical history? • How will operators check if the exposure has been justified and authorised? • How will operators record doses or administered activity if not available on the image files? • Is there a process in place to highlight urgent or incidental findings to the reporting operator?
Clinical evaluation	What arrangements are in place for clinical evaluation? For example: • Who will be responsible for performing clinical evaluations? • Where will clinical evaluation be recorded? • How will incidental or urgent findings be communicated?
Patient safety events	Who will be responsible for the process of managing incidents and near miss events? For example: • How will information be shared? • Who will inform the relevant enforcing authority? • Who will inform the patient or representative? • Who will communicate outcomes, action plan and progress to relevant staff? • How will learning be shared across organisations, where appropriate?
Equipment	Who is responsible for the management of equipment (including software)? For example: • Who will be responsible for the establishment of a QA programme and testing of equipment? • Is there a process for the recording and escalation of faults? • Are there arrangements in place for handover and handing back of equipment?

A4 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 A.4.1 lists the employer's procedures required and provides examples of what the employer may wish to consider for inclusion. This list is not exhaustive.

The employer may provide additional Schedule 2 procedures beyond the minimum required by IR(ME)R. For further information, refer to the main body of this guidance, which should be read in conjunction with this appendix.

Table A.4.1: 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 primary source data are used to check ID?
- What is the process if verbal communication is not possible because of, for example, language barriers, age, mental capacity or being unconscious or sedated?
- Is there more than one operator involved in the examination?
- What is the process if there is a discrepancy with the individual's demographics?
- 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 is the task of entitlement delegated by the employer?
- How is entitlement authorised and who can entitle duty holders?
- How is statutory registration confirmed for referrers and practitioners?
- How are practitioner licences confirmed for practitioners in nuclear medicine?
- How do staff demonstrate their entitlement and scope of practice (including for duty holders working outside of radiology)?
- How are duty holders made aware of their responsibilities under IR(ME)R?
- How are training and competencies assessed and signed off?
- How are individual training records and scope of practice made available (eg training matrix)?
- How often are training, competencies and entitlement records reviewed and by whom?

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Appendix 4

(c) Enquiries to individuals who may be pregnant or breastfeeding

Does the procedure specify:

- Examinations where pregnancy and breastfeeding enquiries are relevant?
- Exceptions where pregnancy checking is not required?
- The cohort of individuals where pregnancy and breastfeeding enquiries are required?
- The age range for pregnancy and breastfeeding enquiries based on local demographics?
- A definition of local high fetal dose procedures (eg greater than 10 mGy)?
- The process to follow if the local decision-making process requires pregnancy testing?
- The process if more than one operator is involved in an exposure?
- The process for patients outside of radiology (eg theatres)?
- The process for unconscious patients and emergency situations?
- How staff will communicate with individuals lacking capacity and those with sensory impairment?
- The process for how enquiries are recorded?
- The process for the optimisation of exposures of pregnant or breastfeeding individuals?
- The process when pregnancy is disclosed in individuals aged under 16 (including support and safeguarding where appropriate)?
- What measures are in place to raise awareness (eg posters, appointment letters)?

(d) Quality assurance programme for written procedures and equipment

Written procedures

- What is the document control authorisation process?
- What should be included within a standard document template (eg version number, author, authorised by, issue date, review date)?
- How often and when are procedures and protocols reviewed?
- Who is responsible for the review process and accuracy of content (including updates to references)?
- How do different staff groups access procedures and protocols (including staff located off site)?
- How are changes communicated to all relevant staff?
- How do staff record they have read or acknowledged a written procedure?

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 equipment taken out and returned to service?
- What is the process for corrective actions when defective or inadequate equipment is identified?
- Who is responsible for the management and QC of equipment outside radiology or nuclear medicine?

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Appendix 4

(e) Assessment of patient dose and administered activity

- What dose information needs to be recorded and where?
- Who is responsible for recording dose (including areas outside of radiology or nuclear medicine)?
- What dose indicators for each modality will be recorded?
- What is the process for setting threshold trigger levels (eg audible alarms)?
- Who is responsible for collating periodic dose data?
- How are dose data periodically audited?

(f) Use and review of diagnostic reference levels

- What DRLs are in place (eg local, national, paediatric)?
- How are DRLs made available to staff?
- How often are DRLs reviewed?
- What is the ratification process and who should be involved?
- 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 (eg documentation, escalation procedure)?
- What DRLs are needed for hybrid imaging?

(g) Research

- What is the process for local research and development approval?
- Does the procedure include a clear description of the research consent process, including consent for radiation exposure(s) and the process for individuals who are unable to consent (eg paediatric patients)?
- What is the process to ensure appropriate employer and practitioner licences for nuclear medicine are in place and reviewed in line with practices?
- Is there a description of how dose constraints are set and adhered to?
- Is there a description of how dose targets are set and monitored?
- How is the participant information sheet made available?
- How are research referrals identified?
- How do duty holders identify research exposures and their associated protocols?
- What is contained in the research file for each trial and how can duty holders' access this?

(h) Written information for nuclear medicine

- When is the information provided to the patient or individual?
- How is the advice on precautions to observe after the exposure provided?
- How is the individual informed of the risks from the exposure?
- 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)?
- 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, information given as part of the consent process)?
- What is the process where verbal communication is not possible?
- Where additional information is provided, how and where is this recorded?

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Appendix 4

(j) Recording of clinical evaluation

- Who records the clinical evaluation and how are they identified (including areas remote from radiology)?
- How and where is clinical evaluation recorded (eg in RIS, PACS or the patient's notes)?
- Does the procedure describe the process for recording the clinical evaluation where a formal radiology report is not issued?
- When should exposure factors be included in the clinical evaluation?
- What happens if clinical evaluation takes place outside the radiology or nuclear medicine department?
- What is the process if software is used to directly assist clinical evaluation?
- 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:

- Governance and escalation structures, including clear arrangements for employer co-operation
- Review of employer's procedures to ensure they reflect local practice
- Adherence to the individual or patient identification process
- Optimisation process
- MPE involvement
- Establishment and use of DRLs
- Optimisation teams
- Effective methods of communication
- Clinical audit
- Compliance audits for all parts of the clinical pathway
- Equipment QA programme in line with recommended guidance
- Training and competency assessments
- Induction programmes for new staff
- Robust entitlement processes
- Peer review of images
- 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 is involved in the investigation and decision-making processes?
- Who will inform the referrer, practitioner and individual (or individual's representative)?
- 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 CSAUE and SAUE 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?

A4

Appendix 4

(m) Non-medical imaging exposures

- If NMI is not performed, is this clearly stated in the employer's procedure?
- Does the procedure include which NMI is carried out locally?
- Does the procedure describe the referral process for NMI exposures?
- How are NMI referrals identified?
- Who will justify and authorise these referrals?
- How are these exposures optimised (eg specific protocols, reduced number of views)?

(n) Carers and comforters

- When may an individual be a designated carer and comforter?
- Who will justify and authorise the exposure?
- What are the dose constraints?
- 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)?
- Are there special considerations for those who would not normally be a carer or comforter (eg pregnant individuals, children acting in a caring role)?

(o) Clinical audit

- How are clinical and IR(ME)R audits defined?
- Are the roles and responsibilities for the clinical audit programme included?
- What is the process for proposing and selecting clinical audit topics?
- How are audit schedules determined and made available once agreed?
- Who is involved in carrying out an audit?
- Who is responsible for audit outcome analysis and identifying appropriate actions?
- How are required actions delegated, carried out and documented?
- How is responsibility assigned for completion and reaudit where necessary?
- How is learning from audits shared with staff members (including staff located outside of radiology or nuclear medicine)?

(p) Making, amending and cancelling referrals

- What referral guidelines are used and how can they be accessed (including those outside the organisation)?
- How can advice be sought on referrals outside the referral guidelines?
- What are the responsibilities of the referrer when completing the referral?
- How are referrals made (electronically, paper based or hybrid)?
- What information must be included in the referral?
- Does the procedure describe the process, responsibilities and required communication when referrals are amended or cancelled by the practitioner or by the referrer

A5 Example training and competency record

This is an example of how a training and competency record could be presented. It is not intended for direct use in the clinical environment but can be adapted by employers to reflect local service provision and practice.

IR(ME)R training and competency record for: [insert name of employee and personnel number]

Name of duty holder
Job title/practice level
Qualification(s) and year obtained
Registration number
Training records held by
Department

Example operator training tasks

Operator training requirements	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				
Correctly identifying patient and recording evidence				
Selecting correct protocol				

This record indicates that the above individual has received training, demonstrated satisfactory knowledge 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.

Example duty holder competency sign-off to establish scope of practice

Competency requirements				
Referrer functions	**Line manager or assessor signature**	**Duty holder signature**	**Evidenced by**	**Date**
Competent to refer for all general radiography examinations				
Competent to refer for nuclear medicine imaging studies			Cross-reference to the relevant register (eg GMC, HCPC, NMC)	
Competent to refer for non-medical imaging examinations			Completion of local or national technical competencies	
Employer's IR(ME)R procedures			1. Initial assessment of understanding of employer's procedures 2. Ongoing audit and review of practice	
Practitioner functions	**Line manager or assessor signature**	**Duty holder signature**	**Evidenced by**	**Date**
Competent to justify exposures for all X-ray general radiography examinations				
Competent to justify exposures for nuclear medicine imaging procedures as outlined in their practitioner licence				
Competent to justify exposures for mammography				
Operator functions	**Line manager or assessor signature**	**Duty holder signature**	**Evidenced by**	**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				

A5

Appendix 5

It is the professional responsibility of the above individual to hold and maintain records of training and competency relevant to the approved scope of practice. Competencies shall be reviewed at a specified time frame, or sooner when the scope of practice changes. The appropriate manager will ensure the competency matrix reflects current scope of practice.

Name and signature of duty holder	Name and signature of entitler	Date completed	Review date

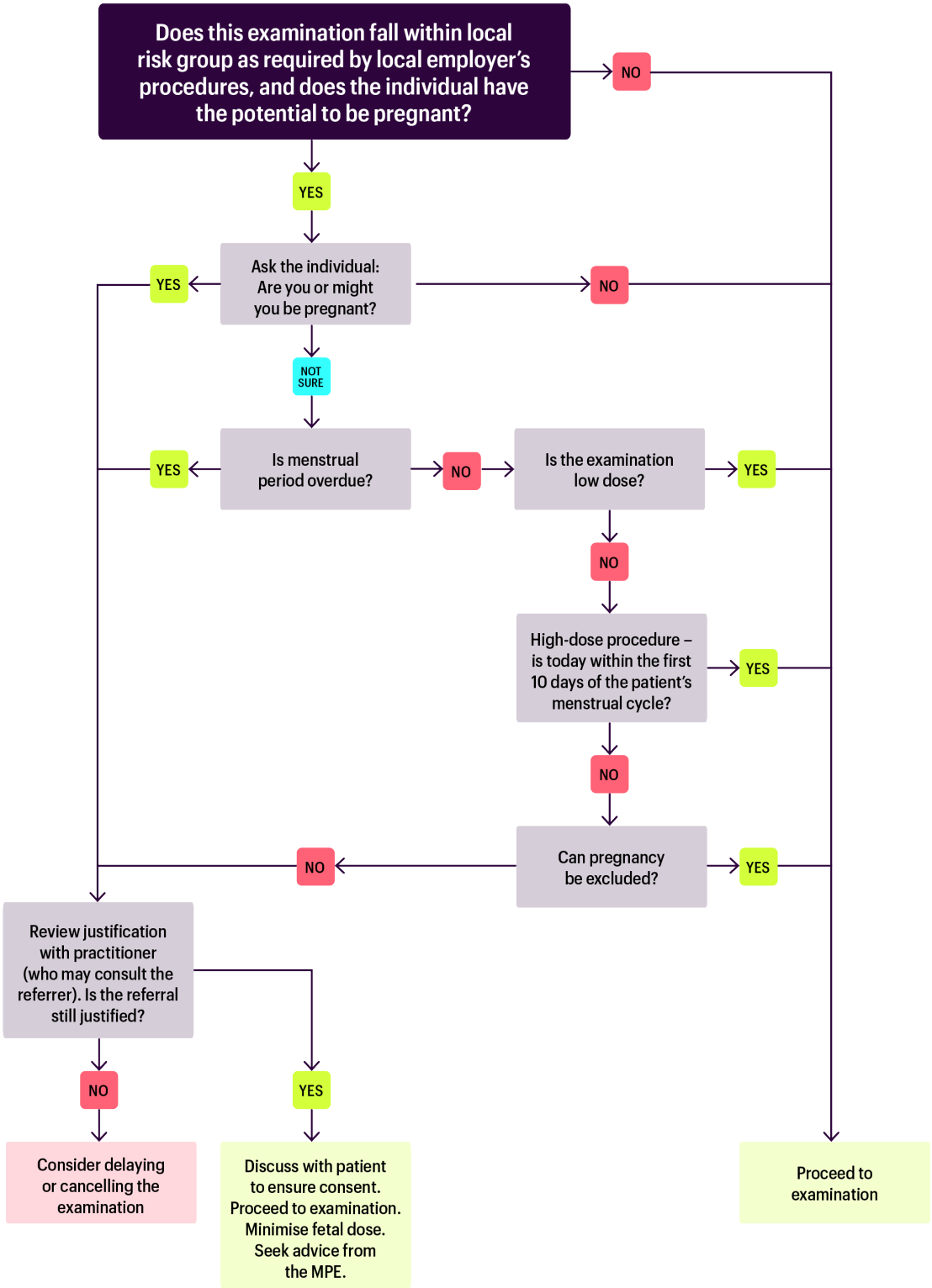
Subsequent review whereby the scope of practice of the duty holder has changed or extended:

Amended entitlement functions	Line manager or assessor signature	Duty holder signature	Evidenced by	Date

Name and signature of duty holder	Name and signature of entitler	Date completed	Review date

A6 Example pregnancy flow chart

This is an example of how a pregnancy flow chart could be presented. It is not intended for direct use in the clinical environment but can be adapted to reflect local procedures.



A7 Working party membership

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	Chelsey Turner
UK Health Security Agency (UKHSA)	Louise Fraser (chair)
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The Royal College of Radiologists (the RCR)	Dr Stephen Harden
	Dr Madava Djearaman
Society and College of Radiographers (SCoR)	Lynda Johnson

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