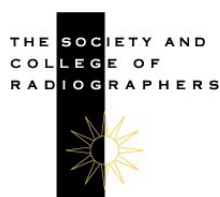


A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology



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Foreword

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 is legislation which provides a framework intended to protect patients from the hazards associated with ionising radiation.¹

In 2008, a joint Royal College of Radiologists (RCR), Society and College of Radiographers (SCoR) and Institute of Physics and Engineering in Medicine (IPEM) document was published offering guidance on IR(ME)R for the radiotherapy community.² This was well received and became a respected guidance document. It is now apparent that practical guidance on the implications of IR(ME)R would benefit the radiology and interventional imaging community.

The RCR, the SCoR, and the BIR (British Institute of Radiology) have therefore produced this guidance, with support from Public Health England (PHE) and IPEM. The IR(ME)R working party brought together representatives from these bodies and sought to produce guidance to help employers and clinical colleagues to understand and implement IR(ME)R legislation as it pertains to clinical imaging in the United Kingdom (UK).

This document explains the principles behind the regulations and endeavours to clarify misconceptions. For the guidance to be user friendly for all staff groups, scenarios have been included to provide examples and advice on practical issues relating to the regulations. The advice given is wide-ranging and does not undermine an employer's legal responsibilities for implementing compliant local procedures.

This document should be read in conjunction with the Ionising Radiation (Medical Exposure) Regulations 2000 and other published guidance.¹

We would like to take this opportunity to thank Dr Peter Riley (RCR), who led the development of this joint publication, alongside Ms Maria Murray (SCoR) and Dr Jonathan Eatough (BIR) and all members of the working party: Mr Andy Scally, Dr Alex Maclennan, Dr David Horton, Dr Andy Rogers, Dr Catrin Ferioli, Ms Gail Woodhouse, Dr Claire Cousins, Ms Sarah Peters and Ms Kathy Slack.

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1. Introduction

This guidance document is intended to provide a **practical approach** to implementing the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) for all staff groups delivering diagnostic and interventional imaging services involving ionising radiation.¹ These groups may include medical directors, chief executives, healthcare professionals, for example radiographers and radiologists, physicists and radiology managers. It also encompasses those providing medical exposures undertaken in areas outside the radiology department, such as in cardiology and imaging performed in operating theatres.

The purpose of the document

It has been recognised that there is a requirement for a comprehensive guide to improve understanding and implementation of IR(ME)R within the clinical imaging community.

This document has been written by representatives from professional bodies, which include radiologists, radiographers and medical physicists in association with PHE. It is hoped this guide will facilitate fuller understanding of IR(ME)R.

IR(ME)R is legislation which places obligations on specific duty holders and provides a framework intended to protect individuals from the hazards associated with medical exposures involving ionising radiation. Breaches of IR(ME)R can result in civil or criminal proceedings, including the serving of Improvement or Prohibition notices (civil action). If the notice is not complied with, this may proceed to prosecution (a criminal activity).

To date, IR(ME)R compliance has not been tested in the courts. As a definitive interpretation of the law can only be established in the courts, the guidance given in this document should be regarded as an expression of professional opinion rather than a definitive statement of the legal position. IR(ME)R does not stipulate how the requirements of the regulations should be implemented. Therefore employers can meet these requirements in many different ways as

long as they can demonstrate that their approach is effective. Readers should not rely on this guidance as if it were a statement of the law and where necessary should seek their own legal advice.

The responsibility for compliance with IR(ME)R lies with the employer and each of the entitled duty holders. The duties and responsibilities of all duty holders are explained in detail and each duty holder has personal responsibility for ensuring the regulations are complied with.

An important aspect of IR(ME)R is that it allows for flexibility and professional judgement to be used as long as the reasoning is clearly defined. Each role and responsibility must be plainly described in written procedures, ensuring everyone is aware of their role and individual scope of practice.

This document seeks to explain the principles of the regulations and clarify some of the common misconceptions which have been highlighted in formal inspections or that have been brought to the attention of the working group by the experience of its members. Scenarios have been included in response to some of the frequently asked questions to clarify common misconceptions and provide examples of good practice. Any text that is directly quoted from the regulations will be in quotation marks.

The regulations

IR(ME)R is derived from the European Council Medical Exposures Directive 97/43/Euratom.³ The regulations are designed to ensure those individuals undergoing medical exposure to ionising radiation are protected from the associated hazards. The regulations in Great Britain are enforced under section 15 of the Health and Safety at Work Act 1974.⁴ In Northern Ireland they are enforced under Article 17 of the Health and Safety at Work (Northern Ireland) Order 1978.⁵

Non-statutory guidance has been produced by the Department of Health (DH) which includes good practice notes to support and clarify

IR(ME)R.⁶ Since the implementation of the regulations, general guidance on the application of IR(ME)R has been published by a variety of organisations for specific areas, such as radiotherapy, dentistry, breast screening and for chiropractors.^{2,7-9} The guidance contained within this document would need to be supported in court by an expert witness but provides a basis for information.

IR(ME)R incorporates the principles of radiological protection as described by the International Commission on Radiological Protection (ICRP) recommendations (ICRP 60 and ICRP 103).^{10,11} For medical exposures, these are justification and optimisation. Dose limits for individuals undergoing medical exposures do not apply as these would not be practical or in the best interest of the patient.

IR(ME)R also requires adequate training for practitioners and operators. The training must relate to the tasks duty holders are required to carry out and be relevant to their scope of practice. This is to ensure that best practice can

be achieved to keep doses as low as reasonably practicable.

IR(ME)R amendments

IR(ME)R has undergone two amendments in Great Britain and one in Northern Ireland since it came into force.

In Great Britain:

- The 2006 amendment changed the definition of the referrer and practitioner and updated some of the requirements around research exposures and training records¹²
- The 2011 amendment explicitly identifies individual health assessments of asymptomatic individuals as medical exposures.¹³

In Northern Ireland:

- The 2010 amendment changed the definition of the referrer and practitioner and updated some of the requirements around research exposures and training records.¹⁴

Definitions – quick reference guide

Authorisation:	Documentation that the process of justification has occurred. Usually demonstrated by a signature/initials on request form or, more frequently now, electronically on radiology information system (RIS) (see section 5).
Clinical evaluation:	'An interpretation of the outcome and implications of, and of the information resulting from, a medical exposure.' ¹ This applies to any evaluation used to direct treatment and does not simply refer to the formal radiological report (see section 11).
Employer:	'Any natural or legal person who carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation.' ¹ Equipment ownership has no impact on the employer responsibilities (see section 2).
Entitlement:	The process of defining the duty holder roles and tasks that individuals are allowed to undertake (see section 3).
Justification:	This is an intellectual process of weighing up the potential benefit of a medical exposure against the detriment for that individual. It must include consideration of techniques which involve less or no ionising radiation (see section 5).

NHS trust:	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
Operator:	Any person who is entitled, in accordance with the employer's procedures, to carry out the practical aspects of a medical exposure (see section 2).
Optimisation:	This is the process by which individual doses are kept as low as reasonably practicable (see section 8).
Policy:	A high level statement governing the conduct of activities in an organisation. Policies outline what will be done with minimal details as to how this will be achieved.
Practitioner:	A registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures (see section 2).
Procedure:	A more detailed description of the control mechanisms for a process indicating detailed management arrangements and responsibilities. Procedures must be complied with by practitioners and operators.
Protocol:	Guidance on the detail of each medical exposure based on a consensus of opinion. They should be specific to each examination and machine. They must be written down and their status clear. Protocols should allow latitude for professional judgement.
Quality assurance:	'Any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and safely complying with agreed standards and includes quality control.' ¹ It does not refer to equipment quality assurance (QA) (see section 18).
Referrer:	A registered healthcare professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposures.
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 (see section 2).

2. Duties and definitions

The employer

IR(ME)R defines the employer as 'any natural or legal person who, in the course of a trade, business or any other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects at a given radiological installation.'¹

It is important to recognise that employer within IR(ME)R relates to health and safety functions rather than employment matters. The employer, as a duty holder under IR(ME)R, is responsible for providing a framework within which professionals undertake their functions (see Appendix 1). This framework is provided through written procedures, written protocols and QA programmes. The employer has a statutory duty to make sure that these are in place and has overall responsibility for ensuring compliance with IR(ME)R.

This also applies to the independent (private) healthcare sector where the hospital senior

manager may be the employer for all staff, including radiologists and clinicians with practicing privileges.

It is commonly seen that the chief executive is described as the employer unless an alternative individual has been designated as the employer. The individual undertaking the role of the employer must hold a senior position within the organisation, usually at board level. The individual's role must relate to all those professional groups that provide elements of the diagnostic and interventional radiology service and ideally should incorporate all other services using ionising radiation such as radiotherapy and nuclear medicine. It is usual for the detailed implementation of IR(ME)R to be delegated to an appropriately trained and experienced professional, for example clinical lead for radiology or medical director, however, the legal responsibility for safe IR(ME)R practice and procedures cannot be delegated and always remains with the employer.

During a radiology IR(ME)R inspection it is noted by the inspector that records of staff having signed to say they have read and agree to follow departmental procedures are incomplete, suggesting that not every practitioner/operator has read and committed to complying with the employer's procedures. The employer, in this scenario the chief executive officer (CEO) of the trust, delegates the task to the radiology clinical director for ensuring this is completed and records maintained. The employer always retains the legal responsibility.

The employer's responsibilities

The duties of the employer are set out in Regulation 4, Regulation 7(8), Regulation 9, Regulation 10 and Regulation 11(4) and are mainly self-explanatory. Under IR(ME)R, the employer is legally responsible, when establishing practices for the safe delivery of a diagnostic and interventional radiology service, for ensuring that robust procedures exist, including those listed in Schedule 1 and (Regulation 4[1]). It is important that procedures are regularly reviewed and updated, for example every two years (Schedule 1[e]).

Such procedures must be documented and must outline the responsibilities of every individual

involved. Appendix 2 includes examples of points for consideration when writing these employer's procedures. The employer must identify who is entitled to act as a referrer, practitioner and operator, and take steps to ensure that all practitioners and operators comply with written procedures. Regulation 4(3)(a) describes how the employer also has responsibility for identifying referral criteria and making sure that these are available to referrers. In diagnostic imaging, referral criteria have been developed and established by the RCR (*iRefer: making the best use of clinical radiology*) which may be supplemented by local departmental referral criteria following agreement by a specialist multidisciplinary team (MDT).¹⁵ Referral criteria

should also include an indication of the expected dose of radiation attributable to each procedure.

Guidelines for referral to interventional radiology for frequently performed procedures are also provided in *iRefer*, together with a broader list of conditions for which such a referral should be considered.¹⁵ In practice, a procedure is usually justified by an experienced practitioner (the interventional radiologist) often following discussion with a clinician or a member of a specialist MDT.

Referral for imaging or an interventional procedure requires a suitably trained and competent registered healthcare professional to assess the available patient information, taking into consideration any relevant previous examination results and alternative imaging modalities.

Those entitled to justify and authorise such a procedure must have this documented in the employer's procedures. For specialist cross-sectional imaging investigations and interventional procedures it may be appropriate to limit this activity to trained competent radiologists.

Additionally the employer is responsible for:

- Having a QA programme in place specifically for documentation – Regulation 4(3)(b)
- Establishing dose constraints for research – Regulation 4(3)(d)
- Ensuring that practitioners and operators are adequately trained and that they engage in continuing professional development (CPD) and education after qualification – Regulation 4(4)
- Investigating and reporting incidents where a dose much greater than intended has been delivered to a patient – Regulation 4(5)
- Ensuring that provision is made within the employer's procedures for the carrying out of clinical audit as appropriate – Regulation 8.

The employer's responsibilities for training

The employer has a responsibility to ensure that practitioners and operators are adequately trained to perform the tasks in their defined scope of practice (Regulation 4(4)(a) and (4(b)) and similarly 'no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained' (Regulation 11[1]).¹

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

Adequate training to achieve and maintain professional registration is determined by the relevant regulatory body as defined in the *National Health Service Reform and Healthcare Professions Act 2002*.¹⁶ For the purposes of demonstrating adequate training to be a duty holder in diagnostic radiology under IR(ME)R, this training needs to have covered both theoretical and practical radiation safety issues specific to diagnostic radiology and any other relevant subjects as outlined in Schedule 2 of IR(ME)R.

Although not a requirement of the regulations, it is often the case that the employer identifies a member of senior staff to have responsibility for IR(ME)R documentation within the organisation. That individual should have these duties detailed within their personal development plan. The responsibilities may also involve the assessment of staff competence where appropriate, maintenance of training records and version control of documentation.

The referrer

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

Referrers are entitled, by the employer, to request that a patient is exposed to ionising radiation as part of an investigative or therapeutic process. Many radiology departments will accept referrals from outside their own organisation for example a general practitioner practice or chiropractor. In this situation, the employer's procedures must state from who they will accept referrals and how the referrer will be provided with referral criteria.

The employer should specify the scope of practice for which an individual can refer. In most situations where the referrer is medically qualified there will be no restriction on what examinations a referrer can request. However, this may vary depending on local arrangements. When a referrer is not medically qualified their scope of practice will usually be for X-ray examinations limited to specific parts of the anatomy.¹⁷ It is important to clarify in written procedures, what examinations may be requested.

A patient is attending a physiotherapist for assessment and treatment of neck pain and stiffness. The physiotherapist refers the patient to the local hospital for an X-ray where there is a documented agreement in the employer's procedures allowing them to make X-ray referrals. However, the patient attends another X-ray department and the referral is declined as the referrer is not recognised by them as a referrer.

A patient attends the emergency department (ED) having had trauma to their right ankle. All ED nurse practitioners in this particular trust are entitled to refer for plain X-ray of the ankle in line with their scope of practice. According to the trust requirements, each individual nurse practitioner must have completed the prescribed training in order to understand, for example, how to use and access the requesting system and their legal responsibilities. They must be deemed competent before they can request imaging within their scope of practice. The employer's procedures must reflect this referral group, their scope of practice and training and competency records should be kept updated.

Physicians' assistants cannot be entitled as referrers under IR(ME)R as they are not registered healthcare professionals.

Information required for a referral

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

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

It is essential that the referrer provides sufficient clinical data to ensure that the exposure can be justified and adequate demographic data so that the referred patient can be correctly identified. This should include full name, date of birth and address.

A diagnostic imaging referral should also include:

- Clinical diagnosis
- Clinical findings on examination
- Any available histology and relevant previous imaging investigations.

A 23-year-old man presents for a chest X-ray. The referral states 'previous imaging demonstrates a pleural effusion in right lung. Planned drainage, reassess please.' The radiographer asks the patient when and where he had his chest X-rayed previously. It becomes apparent that this was only four hours earlier at the community facility when he had been urgently referred to the acute hospital for treatment and further investigation.

The community image is not currently available at the acute hospital. The radiographer feels the examination may not be justified as the image from four hours ago might be adequate to plan treatment. The radiographer discusses this with a radiologist to decide whether this examination should proceed.

In this scenario a repeat chest X-ray would not be indicated as ultrasound examination of the chest could provide the required information. National guidelines also advise that drainage of pleural effusions should be performed under direct ultrasound guidance.

Electronic requesting

The use of electronic requesting (ER) systems has become widespread and has increased access to imaging for users. ER can assist the employer to comply with IR(ME)R by:

- Restricting referral access privileges to entitled referrers only
- Providing the referrer with referral guidelines for medical exposures including information on dose
- Ensuring the referrer provides the required information for the practitioner to justify the procedure

- Providing a record of all requested procedures which can assist the audit process.

These systems rely on a user log-in to identify the referrer rather than a signature. RCR guidance suggests the trust's procedures should ensure it is a disciplinary offence to request a procedure using someone else's log-in, just as it is to request a procedure on a pre-signed request card.¹⁸

Users should receive appropriate training in the use of ER systems to minimise the risk of referrers requesting medical exposures for the incorrect patient.

A trust recognises early in the development of its electronic referral system that there may be significant risks with regard to radiation protection by implementing this new way of working. A full risk assessment is performed and control measures identified to mitigate the risks. These risks include:

- Multiple users referring patients using a single log-in
- Delays in issuing locum staff with user accounts.

The trust policy is amended to reflect the fact that the employer may remove referral rights if password abuse is demonstrated.

The practitioner

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

The practitioner is entitled by the employer to justify and authorise the exposure of a patient to ionising radiation. To perform this action, the request for the exposure is assessed against the clinical data supplied by the referrer. The practitioner must have had adequate training and

be competent to consider the potential detriment of the exposure against the potential benefits for that individual. Previous imaging must also be taken into account if it is of relevance to the current problem. The possibility of alternative modalities which may not involve exposure to ionising radiation must also be considered. Previous imaging examinations should be available for review by the practitioner to allow appropriate justification of the examination.

The practitioner may allocate the task of authorisation of a requested medical exposure to an operator (Regulation 6[5]) but the practitioner retains responsibility for its justification. This requires the operator to follow precisely the authorisation guidelines provided by the practitioner.

A young patient is reviewed at the genetics clinic and is known to suffer from Von Hippel Lindau disease, which puts the patient at increased risk of developing renal cell carcinoma. The clinic refers the patient for an annual assessment and requests a computed tomography (CT) scan. The practitioner, given the patient's clinical history, changes this referral to a magnetic resonance imaging (MRI) scan following discussion with the referring clinician.

It is not uncommon that one person may act as referrer, practitioner and operator, for example, in

dentistry and cardiology. In this situation each role must be separately considered.

A specialist orthopaedic hand surgeon assesses a patient in the fracture clinic where it is decided that the patient requires an operation. The surgeon has access to a mini C-arm in theatre for which he has received practical and theoretical training judged to be adequate by the employer. The surgeon then undertakes the operation using fluoroscopic guidance. At the end of the procedure the surgeon documents the clinical evaluation in the patient's notes stating that 'the fracture was reduced using fluoroscopy. Good position achieved.'

In this scenario the same individual is the entitled referrer, practitioner and operator and is required to fulfil all of those individual roles appropriately,

for example, they must be registered, adequately trained and entitled and must ensure a clinical evaluation is documented in the patient notes.

A newly qualified radiographer receives a referral for a wrist X-ray that does not appear to conform to the departmental justification guidelines to which the radiographer is working. The radiographer is unsure if the examination is justified. In this department there is a lead radiographer who is entitled to act as an IR(ME)R practitioner, justifying general radiography examinations. The newly qualified radiographer seeks advice and discusses the referral with the lead radiographer who reviews clinical information and previous imaging and considers the risk–benefit to the patient. The examination is deemed appropriate and the lead radiographer signs to justify the referral and the examination is performed.

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. It is important that this is defined in written procedures.

It is also the practitioner's responsibility (in conjunction with the operator) to ensure that the radiation dose to the patient is as low as reasonably practicable; this does not mean that the practitioner personally needs to perform an examination or interventional procedure (Regulation 7[1]).

Detriments to be considered in justifying an exposure

The detrimental effects of ionising radiation associated with diagnostic imaging and image-guided interventional procedures are stochastic, essentially cancer induction and tissue reactions (formerly referred to as deterministic effects), mainly skin burns and cataract formation. These risks must be balanced against the potential benefit to the patient.^{19,20} Consideration must also be given to the use of other imaging modalities which do not involve ionising radiation.

Staff should be familiar with these risks from their training and be aware of the thresholds at which skin erythema or cataract formation may occur. They should also be aware of the different susceptibility of various organs to radiation.

Special consideration should be given to young adults, children and females who are or may be pregnant in who risk of cancer is higher due to their tissues being biologically more sensitive.

The operator

The key responsibilities of the operator are outlined in Regulation 5(1) and 5(4), Regulation 7(3) and Regulation 11(1). The definition of operator is stated in IR(ME)R as any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects. The operator does not have to be a registered healthcare professional. Some examples of practical aspects include:

- Operating the imaging equipment
- Patient identification
- Checking pregnancy status
- Clinical evaluation
- Image manipulation and archive.

Operator functions may also be carried out by the medical physics expert (MPE) or other trained medical physics staff including medical physicists and clinical technologists.

The operator is individually responsible for all practical aspects of a procedure that he/she undertakes.

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. Using a matrix is a simple way to demonstrate this, as shown in Appendix 3. Individual training records for operators require regular review as individuals develop and equipment and techniques change.

A medical exposure using ionising radiation must be performed by an operator who has been trained, deemed competent and has been entitled to perform these procedures by the employer. The operator initiating the exposure is responsible for checking the correct patient is being examined. They are also responsible for ensuring the appropriate imaging protocol is used.

Department of Health non-statutory guidance on operators states that, 'Third party service engineers would not normally be considered as operators. Where significant changes to equipment have been made, these should be checked where practicable by an operator (for example, an employee of the NHS trust) before equipment is brought into clinical use.'⁵

In most circumstances in diagnostic radiology, third party engineers, whether providing initial installation or servicing, are responsible for presenting a machine in a safe condition and working to manufacturer's specifications. Following initial installation, third party engineers will release to the trust equipment that conforms to specification and will demonstrate this by presenting data on performance and so on, but further measurements and verification are needed before the equipment can be used clinically. It follows that the third party engineers have undertaken work that will be checked before equipment is used to make medical exposures so the work of third party engineers cannot be considered to directly influence practical aspects of an exposure and therefore they are not considered as operators.

Further assessment is undertaken by those who are responsible, as entitled by the employer, for presenting or returning the equipment in a fit state for clinical use, often a medical physicist employed by the hospital or clinic. These staff collect, provide or verify data that is used directly in determination of scanning parameters during imaging. It is they who are providing supporting aspects to the medical exposure that directly influence the radiation dose delivered to the patient and are therefore operators under IR(ME)R. An example of this would be when a replacement X-ray tube has been installed and medical physicists are required to check performance before the equipment is put back into clinical practice.

Professional responsibility

Each individual duty holder must comply with the employer's procedures. If any duty holder considers that the employer's procedures or practices are unsafe or do not reflect local practice, they have a professional responsibility to bring this to the attention of a senior colleague as defined locally. All duty holders should also be constantly alert to the possibility of an error from any source. Each duty holder should exercise professional responsibility and be encouraged to challenge situations.²¹

A patient arrives in the emergency department in the middle of the night, the on-call radiologist is not on site and a chest X-ray is requested. In this particular hospital the radiographer is able to authorise the examination using guidelines provided by the practitioner who in this case is the person who issued the guidelines.

The guidelines will clearly state the author (possibly by a signature) and the date of issue and review.

Authorisation is the verification or assurance that the process of justification (see section 5) has taken place and is usually demonstrated by the signature or electronic equivalent of the practitioner or operator as described above.

The role of the medical physics expert

A medical physics expert (MPE) is defined in the legislation as someone who holds a science degree or its equivalent and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation. In relation to diagnostic radiology, Regulation 9(2)(c)

A radiographer's individual professional responsibility is to:

- Have and express a professional view, where appropriate
- Be able to challenge, as appropriate, the actions and decisions of others if their performance is likely to result in an ineffective or unsafe delivery of diagnostic imaging services to a patient
- Raise with senior colleagues if it is considered that referrals/practices are unsafe.

Authorisation

Authorisation is not formally defined in the Regulations. Regulation 6(1)(a) requires that all exposures be justified by the practitioner. In addition, Regulation 6(1)(b) requires that no person shall carry out a medical exposure unless it has been authorised by the practitioner or by an operator (who would be working to guidelines provided by the practitioner). Regulation 6(5) permits an operator to authorise an exposure 'in accordance with guidelines issued by the practitioner' if the practitioner is unable to do so.¹

requires the MPE to be 'involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure.'

The MPE, under IR(ME)R, fulfils a similar function to that of the radiation protection advisor (RPA) under the Ionising Radiations Regulations 1999. However, these are two distinct roles and in any given organisation they may or may not be undertaken by the same individual(s). The MPE would normally be a medical physicist, though this is not an explicit requirement of the

legislation. However, implicit in the definition and purpose of this role is the expectation that the MPE's relevant knowledge and experience goes beyond that expected of a practitioner and operator.

More recently, European guidelines on the medical physics expert have been published following the adoption of the updated European Basic Safety Standards Directive.^{22,23}

The role of individuals who are not registered healthcare professionals such as radiography assistant practitioners in practical aspects of the exposure

Suitably trained and competent assistant practitioners (APs) are not registered with a formal regulatory body. They may be accredited by the College of Radiographers (CoR) and entered onto the CoR public voluntary register or they may have completed an in-house training programme and been successfully assessed as competent to carry out specific practical aspects of an exposure. It is important to note that the

term 'practitioner' in this context is different from the term as defined by IR(ME)R.

Once an assistant practitioner has been trained and deemed competent they can be entitled as an operator with a specific scope of practice.²⁴ However, a radiographer should always be available to provide support and advice on radiographic practice. The responsibility for the episode of care for the patient lies with the supervising radiographer.

Before entitling an assistant practitioner to act as an IR(ME)R operator, the employer must ensure that the person is adequately trained and that the training meets the requirements of Schedule 2 of the regulations. The scope of such entitlement must be clearly documented, as it is for all staff groups.

Although assistant practitioners operate professionally under the direction of an health and care professions council (HCPC) registered radiographer, when these individuals are acting as entitled IR(ME)R operators, they are legally responsible for their actions.

3. Entitlement

The definition of the referrer, practitioner and operator are stated within Regulation 2 along with a description of the duty holder roles they are entitled to perform.

Schedule 1(b) describes the requirement for there to be employer's 'procedures to identify individuals entitled to act as referrer or practitioner or operator.'¹

The employer has several obligations under IR(ME)R and one of these is to ensure duty holders are appropriately entitled to perform the tasks required. It is common for the employer to delegate the task of entitling duty holders to another person who is familiar and experienced in the area of practice, for example, the clinical lead in radiology. While the task may be delegated, the legal responsibility always remains with the employer. The lines of delegation from the employer should be clearly documented in the employer's procedures.

It may be appropriate to entitle by staff group, however, each individual in a group must be trained, assessed and entitled before performing the task.

When entitling persons to act as referrers, practitioners and operators, the employer should also specify the extent of their entitlement. This is commonly known as a scope of practice.

Regulation 4(4)(a) says that the employer has a responsibility to ensure their entitled practitioners and operators are adequately trained for what they are entitled to do in their defined scope of practice.

Scope of practice

A scope of practice describes a range of tasks which, when supported by knowledge, training and experience, duty holders will be able to perform while maintaining safe and effective practice. It encompasses the competencies and training required to be permitted to perform specific tasks.

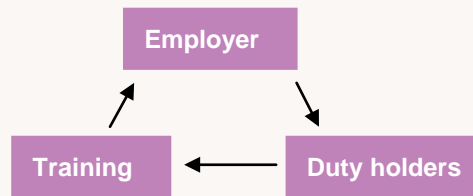
Each duty holder should have a scope of practice outlining the tasks they are entitled to perform and they should be clear about what they are allowed to undertake. This scope of practice should be flexible; for example, when there is a new service requirement or an installation or upgrade of equipment, training, assessment of competencies and scope of practice must be reviewed and updated where appropriate. This also applies when a duty holder has not been involved in a task for a significant period of time.

It is common to see sign off for training, assessments and changes to a scope of practice by the assessor and the employee. Training records, which should be maintained for all practitioners and operators, offer documentary evidence and protection for both the employee and employer. A competence assessor should be familiar with, and experienced in, the tasks and requirements of the duties they are assessing.

See Appendix 3 for examples of scopes of entitlement.

Schedule 2 of IR(ME)R sets out details of the adequate training which practitioners and operators must have completed before they are entitled. Areas of training need only reflect the tasks that the duty holder will undertake.

Figure 1. The process of entitlement



The process of entitlement is described as follows:

- Training supported by training records
- Assessment of competence by an appropriate person – this must be documented
- Entitlement – this may be by staff group (when practicable) or for an individual.

Regulation 11(1) requires that all entitled practitioners and operators must be adequately trained.

An up-to-date record of training and competency in the practical aspects of medical exposures (including dates and nature of training) must be maintained by the employer. This record should

be easily accessible and available for inspection if requested (Regulation 11[4]). It is common practice to see records kept by clinical lead radiologists, radiology managers, heads of physics or MPEs and department superintendents. For ease of access, one person could be identified to keep records for all staff groups.

See Appendix 4 for an example of a local training record.

Referrers and practitioners must be registered healthcare professionals. There is no such requirement for operators although they still need to be adequately trained for the tasks they undertake.

A radiographer, new to a department, for example an interventional room, goes through a period of training and induction. This period includes supervision and competency assessment, by an experienced radiographer, on specific equipment and departmental practices and procedures.

Once the new member of staff has satisfactorily completed all training and competencies and their training records are updated, including dates and nature of training, they can then be entitled to act as an operator in this area. This should be reflected in the entitlement documentation.

The CT clinical lead radiologist in a radiology department is keen to develop staff and improve efficiency within the department. The radiologist spends a period of time training and supervising the CT clinical lead radiographer in the justification of CT head scans for head injury/suspected stroke.

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

4. Training

The employer's responsibility

The employer has a responsibility to ensure that all practitioners and operators are adequately trained to perform the tasks in their defined scope of practice (Regulation 4[4][a] and 4[4][b]). Equally, no practitioner or operator can undertake a medical exposure without having been adequately trained (Regulation 11[1]).

Adequate training

Schedule 2 of IR(ME)R outlines the areas of theoretical and practical training that would be expected to be covered for the training to be considered adequate. It also sets out details of the adequate training which practitioners and operators must have completed before they can be entitled. Areas of training need only reflect the tasks that the duty holder will undertake.

The subject areas in Schedule 2, section A, as relevant to a practitioner's or operator's role, should be covered in adequate breadth and depth so that an individual may function optimally in their role. Section B details supplementary areas of knowledge and training relevant to specific areas of practice (diagnostic radiology, radiotherapy and nuclear medicine). Although initial radiology/radiography training will provide adequate education and practical training relevant to each profession, there will be much

scope for further development in many of these areas and there will be a clear need for supplementary training in some of them. For example, when upgrading an imaging room from computed radiography (CR) to direct radiography (DR) all relevant staff will need to be trained on how to use this new equipment. Similarly, some clinical techniques which were once common are now all but obsolete and have been replaced by new techniques and technologies for which training will be required where this has not formed part of a practitioner's or operator's initial training.

Practitioner training records

Professional qualifications in clinical radiology, for example, Fellowship of the RCR (FRCR) by examination and the subsequent award of a Certificate of Completion of Specialist Training (CCT) by the General Medical Council (GMC), are suitable evidence of competence to act as a practitioner. Practitioners in nuclear medicine require an Administration of Radioactive Substances Advisory Committee (ARSAC) certificate issued on the basis of specialist training and experience.²⁵ 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.

A specialist registrar who is undergoing their second year of specialist training in interventional radiology (IR) would be expected to decide whether a request for an IR procedure is appropriate. They should be aware of the evidence for justifying the request and any alternative examinations involving less or no exposure to ionising radiation. They might also be expected to perform the procedure under direct or indirect supervision.

Registered healthcare professionals, who are not medically qualified, for example radiographers, can be entitled by their employer to act as practitioners. This may be for a defined scope of practice, for example, justification of plain film requests, where it would be impractical for a radiologist to justify and authorise every request submitted to an imaging department. Their formal professional education, training and subsequent

qualification may be used as evidence of the training necessary to perform such roles.

This evidence requires review on an individual basis. It is necessary that this formal training includes benefit versus detriment of exposure to ionising radiation. Consideration should be given locally to any additional training or experience required and the imaging modalities in use.

There is a requirement for additional training and documented training records for both medical and non-medical staff as new technologies are implemented (Regulation 4[4][b]). This requires assessment on an individual basis.

Operator training records

The employer must maintain documented and up-to-date evidence of training. Training records for physicists and radiographers to undertake operator tasks (that is, practical aspects of the

exposure) are often well developed and up to date, reflecting training and competency achieved as they learn different skills.

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

Diagnostic and interventional exposures can only be carried out by an adequately trained, entitled operator. A trainee can undertake such procedures under direct supervision of an entitled operator who is responsible for the task being completed correctly.

All documentation, including scopes of practice and training records, should be maintained and available in the department for staff to access.

In the case of radiographic APs, successful completion of a College of Radiographers CoR approved education course would provide the necessary evidence of adequate training for a defined scope of practice. For those whose training is not CoR approved, a process of AP accreditation may be made to the CoR which, if successful, would also provide evidence.²⁶

In practical terms, for radiographers, proof of adequate initial training will be provided (Regulation 11[2]) by an appropriate qualification that entitles registration with the HCPC.

For radiologists, adequate proof of initial training would be provided by their medical training, supplemented by specialty training, conducted and assessed through the RCR training scheme and leading to the award of a CCT.

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

individual is entitled to carry out. The training should include equipment specific training for all staff groups including radiographers, radiologists, APs, cardiologists, orthopaedic surgeons and anyone else using the equipment.

Medical staff from non-radiology specialties, for example, orthopaedic surgeons and other advanced-skills health professionals may be able to undertake a practitioner role with appropriate theoretical and practical training. They are also able to undertake practical aspects (the operator role) of a medical exposure. Their specialty training may not have included an in depth understanding of the physical and radiobiological principles underpinning the use of ionising radiation. Additional training on certain aspects is required to be able to make the practical decisions necessary to optimise a medical exposure. A formal record of their training must be retained by the employer including:

- The design features of imaging technology
- The effect of exposure parameters on image quality and patient dose
- Appropriate practical training in the operation of imaging equipment.

A diagnostic imaging department employs a short-term agency radiographer to support safe service provision. The employing agency has checked the original qualifications of the radiographer through its own recruitment processes.

Supervision including students and trainees

When an operator task is being performed under supervision, the person supervising has full responsibility as the operator for that task.

For those undergoing training (for example, student radiographers) the requirements of Schedule 2 are unlikely to be fully met and in these cases Regulation 11(3) of IR(ME)R is relevant, where supervision still applies.²⁷

A student radiographer or trainee AP who is not fully trained in a specific aspect cannot act without being directly supervised. In this situation the supervisor may need to be constantly present and observing the task being performed.

It is essential that the supervisor has agreed to oversee a particular task before it commences and that the student or trainee is clear who is supervising them. Since the supervisor, who may, for example, be a radiographer, is taking full responsibility for the task once it is complete, they have the right to decide the level of

supervision required. Very close supervision and observation will be required when the trainee is in the early stages of their training, whereas a student radiographer nearing the end of their training may require only that the procedure they plan to undertake is approved by the supervisor before any radiation exposure takes place.

The SCoR advise that adequate supervision cannot be provided by telephone and if trainees are working in a separate area the supervising radiographer may not be in a position to intervene or provide advice.

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

For trainee radiologists, who will already be medically qualified but not necessarily trained in radiation protection, the scope of their entitlement, as both practitioner and operator, should be commensurate with their knowledge and experience. There also should be clarity as to which aspects of their role require supervision.

A radiology registrar moves from one training department to another. As part of an earlier placement the registrar received training on interventional X-ray equipment and procedures that entitled them to act, for that employer, as an operator and practitioner in that area. The trainee keeps copies of the signed off records. These training records are reviewed by the supervising consultant radiologist in the new work area. Any equipment or procedure differences are highlighted and new training is put in place, assessed and recorded to cover gaps in knowledge or processes.

Training records to be kept for inspection

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

The inspector may ask to see records of:

- Registration and qualification
- Induction
- Equipment specific training
- CPD.

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

Continuing education and training

Even for appropriately qualified staff, the scope of practice for which initial training is adequate will be limited. Regulation 4(4)(b) requires employers to ensure that all practitioners and operators engage in continuing education and training after qualification which is relevant to their role and its development, with particular reference to the clinical use of new techniques and their radiation protection requirements.

Regulation 11(4) states that 'the employer shall keep and have available for inspection by the appropriate authority an up-to-date record of all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures ... showing the date or dates on which training qualifying as adequate training was completed and the nature of the training.' This should include further relevant postgraduate training and qualifications, in-house training and attendance at external training events, seminars, conferences and so on. Although not mentioned explicitly in the regulations, the employer could have a procedure for periodically reviewing the training records of

all staff entitled to act in the practitioner and/or operator role and for assessing the adequacy, currency and completeness of staff training. This is particularly important when the introduction of new clinical techniques or technology is planned.

Training for referrers

Formal training is not a legal requirement for referrers, though professional guidance has been published by an alliance of health professional organisations including the RCR, SCoR and the Royal College of Nursing (RCN), that advocates local training for non-medical referrers in conjunction with the clinical imaging service provider and medical physics department.¹⁶ It is commonly seen that non-medical referrers (for example, emergency department nurse practitioners) undergo locally agreed and appropriate training before being entitled as referrers for a specific scope of practice. Training for referrers is helpful when, for instance, an organisation introduces electronic requesting into its radiology service. Advantages include clarification of the clinical information required, how to cancel requests and how to access referral criteria.

5. Justification and authorisation

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

When justifying an exposure, there are a number of considerations for healthcare professionals to take into account, for example, will the exposure contribute to or change the individual's healthcare management, what relevant previous

imaging is available and are there alternative techniques that will answer the question but do not involve ionising radiation?

Regulation 6(1) says that a medical exposure may not be carried out unless it has been justified and authorised. This means that all medical exposures on each individual must be justified and authorised before being undertaken.

Justification is an intellectual activity and is the primary role of the practitioner. When justifying an exposure, appropriate weight must be given to the matters outlined in the Table 1.

Table 1. Considerations for justification of medical exposure to ionising radiation

IR(ME)R Regulation 6(2)		Consider
a	The specific objectives of the exposure	What is to be gained by carrying out the exposure? How may the outcome affect the management of the patient?
b	The characteristics of the individual involved	Such as previous imaging, medical history, age or pregnancy status of the patient, body habitus.
c	The potential diagnostic or therapeutic benefits to the individual from the exposure	What is the expected benefit of the medical exposure? Will the patient's treatment be altered?
d	The detriment the exposure may cause	What is the possible detriment from the associated radiation dose?
e	The efficacy, benefits and risk of alternative techniques having the same objective but involving no or less exposure to ionising radiation	What other alternative imaging modalities are available that could answer the diagnostic question but involve less or no radiation?

Authorisation is the documentation that the intellectual activity of justification has taken place. Authorisation may be carried out by either the practitioner or an operator working to guidelines issued by the practitioner (Regulation 6[5]). It may be demonstrated by, for example, signing or initialling the referral in a predetermined place or by entering an electronic password. The employer's procedures should describe clearly how authorisation is to be demonstrated.

When the regulations came into force, it was neither efficient nor feasible for a radiologist, as a

practitioner, to review every imaging request, therefore the regulations allowed for an appropriately entitled operator to authorise an exposure using guidelines that a practitioner has written. For the purposes of this document these will be referred to as authorisation guidelines.

NB When employing this approach, the practitioner remains responsible for the justification element while the operator is responsible for authorisation and following the guidelines.

Since the regulations came into force, practice has changed and, in many centres, radiographers and some other healthcare professionals, for example, orthopaedic surgeons and speech and language therapists, are now entitled as practitioners for a specific range of diagnostic procedures.

Authorisation guidelines

Authorisation guidelines must be produced by a named practitioner (often, but not always, the lead radiologist). The individual who produces these guidelines takes responsibility for any exposure authorised using these guidelines that is they are the practitioner. The author and review/revision dates should be clearly stated. The guidelines should reflect the most current accepted practice and take into account local service provision. In a hospital that has a number of subspecialty areas such as paediatric

radiology, neuroradiology or cardiology, there may be a set of authorisation guidelines for each area, each produced by a different practitioner. In some imaging departments, guidelines may be used in one area, say CT scanning, but not in others, such as general radiography. However, where they are used, the person responsible for authorising under the guidelines must be clearly identified and appropriately entitled as an operator in the employers procedures.

While referral guidelines such as those produced by the RCR (for example, *iRefer*) are not sufficiently detailed for use as local authorisation guidelines, they could be considered to be a suitable starting point for their development. See Appendix 5 for an example of authorisation guidelines.²⁸

In general radiography, a referral is received by a radiographer who will review the clinical information provided by the referrer, together with the question the referrer needs to answer. The radiographer, acting as the practitioner, will consider the benefit of the medical exposure as well as any potential risk associated with that use of ionising radiation. If the radiographer considers the procedure to be justified they will authorise the exposure which can then be carried out.

In this scenario the radiographer is acting as the practitioner in justifying as well as the operator in authorising the medical exposure. They must be

appropriately entitled by the employer to do so within a defined scope of practice.

A CT scanning unit receives a referral which is reviewed by a radiographer to check 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 matches the 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 medical exposure. The radiographer is acting as an operator authorising the medical exposure against the guidelines. The radiographer may or may not be the same operator who then carries out the exposure. Both the radiologist and the radiographer must be appropriately entitled in their respective capacities by the employer to act within a defined scope of practice.

use these guidelines, they are acting outside the hospital's agreed framework and their entitlement and may be in breach of the legislation. Healthcare professionals can only legally function as practitioners if they are entitled to do so. Entitlement by the employer offers a level of protection for both the employer and employee; the employer is assured that staff members are working within a defined and agreed scope of practice and the individual staff members cannot be forced to do anything for which they are not entitled or trained.

It should be noted that if an employer has decided that authorisation guidelines are to be used, if operators (such as radiographers) do not

Vetting

This term is commonly confused with justification, however, these may be separate activities that occur at different stages in the imaging pathway. The term vetting is not referred to in IR(ME)R and it is not synonymous with the process of justification. Vetting is a term often used for those procedures that require a patient appointment, such as CT scanning or fluoroscopic examinations and is linked to the scheduling of an examination; however, this does not mean that the examination has been justified. It should be noted that irrespective of the process used, all

medical exposures must be justified by an appropriately trained and entitled practitioner before the exposure takes place. Vetting describes different activities for different imaging departments. It can describe, for example, booking/scheduling, setting protocols, justifying/authorising or checking previous imaging. It is important to clarify the process of 'vetting' for each trust or imaging department and this should be clearly described in local procedures.

A referral for a CT scan is checked for completeness and scheduled by a radiographer. The supervising radiologist reviews all the referrals for that session and justifies and authorises each one in advance of the scan taking place. The radiologist will be the practitioner for the examinations performed during that session.

On some occasions, a radiologist may be responsible only for the 'vetting' or checking of a referral such as a CT scan. On others, it may be that more than one radiologist is involved in the

justification of a procedure. It is possible to have two people who are responsible for the justification of different parts of the scan. This must be clearly recorded.

A referral for a CT scan of the head is checked by a radiologist, who simultaneously justifies, authorises and protocols the scan. The patient is then booked onto a session supervised by a different radiologist. On attendance the patient undergoes the CT scan as indicated by the first radiologist. On reviewing the images, the radiologist supervising that CT list decides that a second, post-contrast CT scan of the same area is required and this is carried out. The checking radiologist is responsible for the justification of the first pre-contrast scan. The supervising radiologist is responsible for the second post-contrast scan. A clear record must be made of each practitioner's involvement in the justification of this scan.

6. Patient identification

Schedule 1(a) requires the employer to establish 'procedures to identify correctly the individual to be exposed to ionising radiation.' Guidance is available for the process of patient identification.^{29,30}

For the majority of requested examinations, direct questioning of the patient requiring an active response would be deemed to be appropriate and adequate. Typically, the questions to be asked would be:

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

All responses must match the information provided on the request form.

Table 2. Alternative methods of patient identification

Patient type	Things to consider
Unconscious patients	Could hospital wristbands be used? Cross reference hospital unknown patient and major incident policies.
Theatre patients	With who does the radiographer confirm patient ID? The anaesthetist? The nurse in charge of the theatre? The surgeon?
Patients with mental capacity issues and those under the influence of drugs or unable to respond	Could patient identification be checked with an accompanying person?
Patients with sensory impairment	Could ID be checked using written cards? Could other forms of ID, for example, a photo ID driving licence, be used?
Speakers of other languages or patients with inadequate command of English	How can staff access hospital translation services?
Paediatric patients	Could patient identification be completed with an accompanying nurse, carer or parent if the child is unable to answer all of the questions?

Correct identification of the patient is an operator task which must be undertaken before any medical exposure is made, however, correct identification of the patient always starts with the referrer. The operator undertaking this responsibility must be identifiable by their signature on the request form or electronically on the radiology information system (RIS).

There are several circumstances under which this procedure would not be appropriate or possible to implement; it is important that these eventualities are anticipated and the employer's procedure identifies alternative means of satisfactorily establishing the correct identity of the patient. Some examples of how this could be achieved are included in Table 2.

In all circumstances, the operator should assess whether the clinical information provided by the referrer to inform the justification process is in

accordance with the patient's understanding of the reasons for their referral.

7. Pregnancy enquiries

Schedule 1(d) requires the employer to ensure there are 'procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant,' while Regulation 6(1)(e) says that no one can carry out a medical exposure without first checking whether females of childbearing age may be pregnant. Regulation 6(3)(c)(i) requires the practitioner to pay special attention when justifying an exposure for a female where pregnancy cannot be excluded.

Regulation 7(7)(e) states that the practitioner and operator must pay special attention to the optimisation of exposures, where appropriate, to 'females in whom pregnancy cannot be excluded and who are undergoing a medical exposure, in particular, if abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child.

Making pregnancy enquiries in advance of a medical exposure is an operator task. IR(ME)R states that these enquiries should be made 'if relevant' therefore it is for the employer to describe when and how pregnancy enquiries should be made.

In many radiology departments it is seen that pregnancy enquiries are only required for examinations on females within the age range 12–55 years, where the primary beam may irradiate the pelvis (that is, those examinations involving the area between the diaphragm and knees). However, some departments have liaised with their trust obstetrics team to set an age range that more accurately reflects local patient demographics. Establishing pregnancy status can be a sensitive matter, especially when asking those under the age of 16 years. Consideration should be given as to where and how these personal questions are delivered for all female patients.

When a female who falls into the category where pregnancy enquiries are required attends for a medical exposure, she should be asked whether she is or might be pregnant. This question is likely to result in one of three answers; 'No,' 'Yes,' or 'I'm not sure.'

Where the patient is unsure about her pregnancy status, many departments will apply either the '28-day rule' or the '10-day rule' depending on the examination that has been requested.

For examinations considered to be high dose (usually CT scans involving the abdomen and pelvis and a few nuclear medicine examinations) the 10-day rule is often applied as it is unlikely that a female will become pregnant during the first 10 days of her menstrual cycle. The employer's procedures should clearly define the examinations classed as high dose where the 10-day rule must be used.

For all other relevant examinations the 28-day rule is used. In the case of the 28-day rule if a female's period is not overdue then the examination can continue. Consideration could also be given to deferring the examination when there is uncertainty but this will be influenced by the urgency of the examination. Further information has been produced jointly by the HPA, the RCR and the SCoR.²⁸

Some departments also incorporate the use of pregnancy testing as part of their pregnancy enquiries procedure. Guidance is available on the use and accuracy of pregnancy testing.³¹

Table 3 describes actions that departments might take dependent on the response to the pregnancy enquiry. An example of a pregnancy enquiries flow chart can be found in Appendix 7.

Table 3. Pregnancy enquiry responses and possible actions

Pregnancy status	Possible action
Definitely not pregnant	Proceed with the examination.
Definitely/Probably pregnant	<p>Operator to discuss the examination with a radiologist and possibly the medical physics department to decide whether the exposure could be further optimised, taking into consideration the potential exposure of the unborn child.</p> <p>This could include using a different modality, reducing the number of images taken and using facilities such as 'fluoro grab.'</p> <p>Consideration could be given to deferring the examination if not urgent.</p> <p>Requires sign off before examination proceeds by the practitioner.</p>
Unsure	<p>Apply 10/28-day rule as appropriate.</p> <p>Consideration could be given to deferring the examination if not urgent.</p> <p>If the patient's period is overdue, consideration could be given to the use of a pregnancy test, in discussion with the referrer and the practitioner justifying the examination.</p>

The process for making pregnancy enquiries should be described in an employer's procedure (Schedule 1[d]). The procedure should cover the areas discussed previously in this section but should also include matters such as what happens in emergency situations where it is not possible to ascertain pregnancy status. The employer's procedure should also include how to make enquiries where there is a communication barrier such as an unconscious patient, patients for who there is a language barrier and those with special needs, in a similar way to when checking patient identification (see Table 2 in section 6).

The response to pregnancy enquiries should be documented as evidence that the appropriate questions have been asked.

Staff may also find it helpful if references to any paediatric and vulnerable adult safe-guarding policies are included in the employer's procedure.

Inadvertent fetal exposures

Inadvertent fetal exposures can arise in two circumstances.

- At the time of the examination the operator was assured by the patient that there was no possibility of pregnancy and/or the employer's procedure was correctly followed.
- At the time of exposure no enquiry was made about the patient's pregnancy status, contrary to the employer's procedure.

Following an inadvertent fetal exposure, an investigation is required, often with input from the MPE. Counselling of the patient by the relevant radiologist/clinician, particularly in the case of higher fetal doses, and with sending relevant information to the patient's GP, may be helpful once the investigation has been completed.

Failure to comply with an employer's procedure for making pregnancy enquiries that leads to an inadvertent fetal exposure could be considered to be a breach of regulations. These instances should be notified to the appropriate inspectorate. The reporting of inadvertent fetal exposures where there has been no breach of IR(ME)R is to be encouraged as it demonstrates a culture of openness.

8. Optimisation

All medical exposures require optimisation.

The optimisation process is the joint responsibility of the practitioner and operator and requirements for optimisation of medical exposures are described in Regulation 7.

Regulation 7(1) states that 'the practitioner and operator ... shall ensure that the doses ... are kept as low as reasonably practicable (ALARP) consistent with the intended outcome.'¹

Deciding the appropriate dose for each individual exposure involves team work. Radiographers, radiologists, medical practitioners, other non-radiology staff (such as cardiologists) and

medical physicists should work with manufacturers and application specialists to ensure new (and updated) equipment is optimised. Exposures and protocols may require modification to meet local image-quality standards while giving due consideration to keeping patient doses ALARP.

Optimisation should be reviewed on a regular basis if practice changes or when equipment is updated. Staff training should be considered and included in the optimisation process.

The table below describes areas for consideration when optimising medical exposures, however, this list is not exhaustive.

Table 4. Optimising medical exposures

Optimisation	Things to consider
Training Regulation 11(1)	There is a robust training programme in place to ensure all operators are competent and aware of new or updated equipment.
Protocols Regulation 4(2)	Written protocols are in place to ensure the appropriate technique is performed to answer the clinical question.
Equipment Regulation 7(3)	Equipment appropriate for the purpose is selected and due consideration is given to ensuring each medical exposure is ALARP.
MPE advice Regulation 9(c)	MPE to be consulted on optimisation including patient doses and protocols.
Clinical audit Regulation 8	Image quality and technique may be audited and learning shared.

Regulation 5(6) makes it clear that the optimisation process, as it relates to practical aspects of the exposure, may require co-operation with other specialist staff. In practical terms, this could involve consultation with the medical physics expert on technical issues such as protocol optimisation or the referrer should further clinical details influence a more tailored examination and reduce the dose to the patient.

Regulation 7(7) explains that the practitioner and operator are required to pay special attention to the optimisation of medical exposures. Table 5 includes some areas for consideration.

Table 5. Optimisation of medical exposures

Special attention	Things to consider
Doses for medico-legal exposures are ALARP	Medico-legal exposures may have specific protocols involving fewer projections.
Exposures of children	Appropriate protocols are available for several paediatric size, weight, age or body mass index (BMI) ranges.
Exposures in a health-screening programme	Exposures may have strict inclusion criteria and there is a comprehensive image-quality assurance programme in place.
Exposures involving high doses	Consider using dual-phase contrast for trauma CT scan, thereby reducing the number of scan 'runs' required.
Females where pregnancy cannot be excluded	These exposures may be justified and protocolled by a consultant radiologist with advice from the MPE.

While standard protocols should be determined through an optimisation process, operators are still required to use their professional judgement

and adjust technique and exposure parameters according to patient age, size or other pertinent clinical information.

9. Diagnostic reference levels

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

DRLs are used as a guide to help promote improvements in radiation protection practice. They can help to identify issues relating to equipment or practice by highlighting unusually high radiation doses. DRLs are a trigger to one of the steps of optimisation of patient dose and are not expected to be exceeded when good and normal practice is applied.

DRLs are average dose levels for typical diagnostic examinations on standard size adult patients and are not individual patient doses. They should be used in addition to professional judgement.

Regulation 4(3)(c) says that the employer must establish diagnostic reference levels (DRLs) for examinations applying to individuals undergoing:

- Medical diagnosis or treatment
- Occupational health surveillance
- Health-screening programmes
- Medico legal exposures.

National DRLs (NDRLs)

While European DRLs are available, National DRLs may better reflect UK practice and these should be considered when establishing dose levels.³² National DRLs are reviewed and formally adopted by the Department of Health from national dose surveys using data submitted by hospitals in the UK.^{33–35}

Local DRLs (LDRLs)

Local dose surveys can be carried out by, for example, medical physicists or radiographers. Advice should be sought from the MPE about setting levels to reflect local practice, equipment and patient cohorts. These dose levels could be provided to the employer to be used as LDRLs and ideally should be reviewed as part of a regular dose-audit programme or when new equipment is installed or if clinical practice changes.

Consideration should be given to setting LDRLs for children for commonly requested examinations.³⁶

An employer may decide to adopt NDRLs or choose to set LDRLs, however, if the latter are higher than those set nationally an investigation and explanation would be required.

A radiographer in a general X-ray room notes that exposures for chest X-rays in the room he/she is working in today are consistently higher than the LDRL. Chest X-rays performed in another general room on the previous day were noted to be generally lower or the same as the LDRL. The radiology manager is informed and an initial investigation is carried out. This confirms there is a disparity and the medical physics department is notified. Further equipment tests are performed and an analysis provided.

Having the adopted DRLs displayed in the work area demonstrates good practice.

Table 6. DRL regulations and recommendations

Special attention	Things to consider
<p>Regulation 4(6)</p> <p>The employer shall undertake appropriate reviews whenever diagnostic reference levels are consistently exceeded and shall ensure that corrective action is taken where appropriate.</p>	<p>Provide a process for how staff should report consistently exceeded DRLs.</p>
<p>Regulation 4(1) and Schedule1(g)</p> <p>Adopted DRLs are not expected to be exceeded for standard procedures when good and normal practice is applied.</p>	<p>The employer must have a written procedure describing the adopted DRLs, how they should be used and what to do if they are consistently exceeded.</p>
<p>Regulation 7(3)(c)</p> <p>Appropriate equipment should be chosen and methods to ensure patient doses are kept ALARP, taking in to consideration the diagnostic purpose.</p>	<p>Procedures for assessing equipment when tendering.</p> <p>Regular review of optimisation.</p>
<p>The operator should pay special attention to adhering to the adopted DRLs.</p>	<p>DRLs available and visible at every control area.</p>

10. Patient dose assessment and recording

Under IR(ME)R, the method of assessment and recording of patient doses by an employer must be specified in their procedures. It is also a requirement that an operator should pay special attention to patient dose when selecting equipment or methods to expose an individual (Regulation 7[3]).

As well as the need to ensure compliance with the regulations, recording and assessing patient dose may be necessary for a number of different reasons. This could be to:

- Assist with dose optimisation
- Compare against or establish diagnostic reference levels
- Enable the operator to determine if a dose has been given which is much greater than intended
- Satisfy an ethics committee for the use of radiation in research
- Compare different techniques or equipment.

Best practice is to ensure that individual patient exposure information is recorded for each exposure. Since 2000, there has been a legal requirement under The Ionising Radiations Regulations 1999 (IRR99) for the manufacturers of equipment to provide the user with a suitable means of informing the operator of the quantity of radiation produced during a radiological procedure.³⁷ Most modern equipment will display

a dose indicator, which is dependent on the modality, this can be recorded on the patient record or referral card and is available within the digital imaging and communications in medicine (DICOM) header of the image when stored on the picture archiving and communications system (PACS).

The quantity dose area product (DAP), which is defined as absorbed dose to air, averaged over the area of the X-ray beam, multiplied by the beam area, is most commonly used for general radiology and fluoroscopy. It is displayed in units of Grey.centimetres² (Gy.cm²) or various sub-multiples. Operators must be aware of the units for their particular system and ensure they are noted in the patient record.

For old equipment or that which does not have a DAP display, a record of kilovolts (kV) and post-exposure mAs, should be made. It may only be necessary to record the exposure factors where there has been deviation from the standard protocol.

For CT, the dose quantity displayed is dose length product (DLP) or CT dose index (CTDI).

The employer should seek advice from the local MPE about the most appropriate methods for recording and assessing the patient dose for the systems that they have in place.

11. Clinical evaluation

The term evaluation is defined in Regulation 2(1) as the 'interpretation of the outcome and implications of, and of the information resulting from, a medical exposure.'¹

Clinical evaluation is most commonly considered to be a written radiology report, which is frequently recorded on the RIS. It may, also include entitled radiographers and other healthcare professionals who provide initial image interpretation which could support ongoing patient management.³⁸

There are instances where evaluation is recorded directly in the patient's clinical notes. Any assessment of an image that has an impact on patient management should be considered a clinical evaluation.

Regulation 7(8) requires the employer to ensure that a clinical evaluation and factors relevant to dose, for example exposure factors, are recorded. Schedule 1(j) states that the employer must have 'procedures for the carrying out and

recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose.' Adherence to these tasks could be assessed through audit (Regulation 8).

Non-statutory IR(ME)R guidance (Section 9.10.3) recommends that relevant dose factors, which may include exposure time, are recorded so that an estimation of effective dose can be calculated at a later date if required.⁵ This information should be easily accessible and, while, these exposure factors do not form part of the formal evaluation, they are often seen recorded on the RIS by the operator.

Clinical evaluation is considered to be an entitled operator function and this must be reflected in the scope of practice.

A mobile chest X-ray is performed on an intensive care unit (ICU) following insertion of a central venous pressure line (CVP) line. To effectively manage patient treatment, the image is clinically evaluated on the unit by a suitably trained and entitled (documented in the employer's procedures as an operator for the purpose of clinical evaluation) 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. In this scenario it may be that no further written evaluation (report) from radiology is required.

An orthopaedic surgeon refers a patient for an X-ray of their wrist in plaster to assess union of a scaphoid fracture. Immediately following the X-ray procedure the patient returns to outpatients for the result. The orthopaedic surgeon reviews the images, sends the patient for the cast to be removed and records in the patients notes his evaluation of the images. To be able to perform this task, the surgeon must be deemed competent and be entitled as an operator in the employers procedures. To ensure the employers procedures are complied with, the radiology department performs regular (annual) audit of evaluations not recorded on the RIS.

An orthopaedic surgeon performing a hip pinning in theatre uses fluoroscopic guidance to accurately position the pins. The operation is satisfactorily completed and the surgeon records the screening evaluation in the patient's postoperative notes. The radiographer involved with the fluoroscopy records dose-related factors, such as screening time, on the RIS. The radiology department undertakes regular audit of patient notes to monitor whether the evaluation process is being performed appropriately.

Where image interpretation is undertaken by non-radiology staff (for example cardiologists, orthopaedic surgeons, dentists or chiropractors) the employer, through their procedures, must reflect who is delegated the task of ensuring the expertise and appropriate training of these individuals to provide a clinical evaluation of an exposure. It is often the case that medical directors or clinical leads for a specialty may be

delegated the task for this group of medical practitioners.

The RCR has produced standards for the reporting and interpretation by non-radiologist medically qualified practitioners.³⁹

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

12. Research

The regulations contain a number of requirements that must be met in addition to those that apply to all medical exposures. These research-specific requirements are described in Regulations 4(3)(d), 6(1)(c) and 7(4). Additionally, Regulation 6(3)(b) applies to individuals for who there is no health benefit, including healthy volunteers.

The requirements are that:

- All research programmes must be approved by an ethics committee before commencing
- The individuals concerned must participate voluntarily
- The individuals must be told in advance about the risks of the exposure

- Individual target levels of dose are planned where the participants are expected to receive a medical benefit
- A dose constraint must be in place for individuals where no direct medical benefit is expected
- Any dose constraint is adhered to
- The practitioner pays special attention to the justification of exposures that have no direct health benefit for the individual.

The employer is also required to have in place a written procedure regarding medical exposures for research purposes (Schedule 1[h]). Table 7 lists the requirements under the regulations and gives some examples of how the written procedure could describe how they may be addressed in practice.

Table 7. IR(ME)R research requirements

Requirement	Things to consider
Approval by an ethics committee	A description of the ethics process including any local research and development approval process.
Individuals participate voluntarily	A description of the research consent process.
Individuals informed in advance about the risks of the exposure	The participant information sheet (PIS).
Dose constraints	Are research programmes where no direct medical benefit is expected (for example, studies on healthy volunteers) undertaken at this institution? If they are not then dose constraints do not apply.
Dose constraints are adhered to	Periodic dose audits.
Individual levels of target dose	How are operators informed about the target dose for each research programme?
Special attention	Applicable where no direct medical benefit is expected that is, studies on healthy volunteers.

The first question that needs to be addressed when designing a research study is 'Does this study include a research exposure?' The National Research Ethics Service (NRES) has issued guidance which defines a research exposure as:

'Any exposure required by the research protocol following initial consent from the participant. It

includes all exposures carried out on the participant as determined by the protocol, including those which would otherwise be part of routine clinical care for patients treated outside the research setting.'⁴⁰

The following scenarios include some examples of research exposures that are commonly encountered in a radiology department.

A 25-year-old male is invited to be considered for inclusion on a clinical trial in human immunodeficiency virus (HIV) infection. The trial eligibility precludes patients with tuberculosis (TB). Potential participants must have a chest X-ray to exclude TB before recruitment onto the trial.

This medical exposure is a research exposure as the X-ray is an integral part of the protocol to inform decisions about study eligibility.

A study is carried out investigating patient reactions following administration of different types of X-ray contrast media during CT examinations which are undertaken as part of a course of standard care.

The medical exposure is justified and authorised as part of normal clinical care outside the context of the research therefore this is not a research exposure.

A physiology student is undertaking a Masters of Science (MSc) study involving tests on healthy volunteers. Dual-energy X-ray absorptiometry (DXA) scans will be carried out in accordance with standard protocols in place at the university. While exposure from one DXA scan may be minimal, the study involves radiation as an integral part of the protocol and this is a research exposure.

DXA scans are seen in university research in disciplines such as physiology. Although the research may be undertaken with healthy volunteers rather than NHS patients, research ethics committee (REC) approval of such research is a legal requirement under IR(ME)R.

A manufacturer-led clinical investigation is being undertaken for CE marking of a novel cardiac stent for treatment of patients with coronary heart disease, requiring X-ray guided insertion of the device. Requirement for a stent is part of the inclusion criteria and normal care outside the study would also involve X-ray guided insertion of a standard stent.

The radiation exposure is integral to the procedure required to undertake the investigation and will be authorised in the context of participation in the research rather than as part of normal clinical care. This position is not altered by the fact that the same procedure would be received outside the study by a patient opting not to take part. This is a research exposure. *NB* Although X-rays are used in standard care, there may be changes in the radiation dose delivered to study participants due to the novelty of the device.

A clinical trial will use MRI scans to assess response to treatment. The standard screening for contraindications to MRI includes questions to check whether patients could have metallic foreign bodies present in biologically sensitive areas. Patients presenting with this possibility will be referred for X-ray.

The MRI scans are required by the protocol to assess the study endpoints and are an integral part of the research. If a patient requires an X-ray to take part in the study, this would be a research exposure.

Studies have found that the presence of metallic objects is extremely low in the general population. Therefore, unless the study targets a population in who this is likely to be a feature (for example, wounded military personnel), the simplest approach would be to exclude patients presenting with the need for X-ray. The study would not then involve radiation exposure.

Ethics committee approval

Before any research can go ahead it must have ethics committee approval. Detailed information on this process can be found via the NRES website.⁴¹

NB Ethics committee approval does not automatically mean that all the research exposures included in the study have been justified and authorised on an individual patient level. These are separate activities.

Practical considerations

It is important that radiology staff can identify those exposures that are for research purposes. This can be achieved in several ways, for example 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 specific protocol is required for each research programme. This should include:
- The dose constraint or target dose as appropriate
- The number and type of required exposures.

These protocols should be readily available to staff. It may helpful to consider having a radiology research file where all documentation can be easily accessed. The file could also include contact details of the local research team members, the expected end date of the trial and a copy of the ethics approval.

Regular communication between the radiology department and the research team should be encouraged.

13. Health screening

Regulation 3(c) applies to medical exposures performed on individuals as part of a health-screening programme, including any exposure of an asymptomatic individual.

Health screening relating to IR(ME)R is the process of using ionising radiation to identify a disease or condition in apparently healthy people who are considered to be at increased risk.

The investigation of asymptomatic individuals falls into two categories.

Screening programmes

These are national screening programmes where the potential benefits of screening a specific group of people have been assessed and compared to any detriment for the population as a whole.

The programmes are evidenced based with stringent quality requirements and defined referral criteria for those who will be invited for screening. They take into account the need to provide adequate information to those offered the service and have clearly defined care pathways in place for individuals who may require further investigation or treatment.

An example of this would be the National Breast Screening Programme.

Individual health assessment (IHA)

In 2011 the Department of Health amended IR(ME)R to explicitly include individual health assessment within the scope of the regulations.¹²

This term is used for investigations on asymptomatic individuals who may consider they are at risk from disease and wish to exclude any unknown underlying health issues. Individual health assessments (IHAs) are directed at individuals rather than groups or populations.

The requirements of IR(ME)R, which include complying with processes for referral, justification, optimisation and evaluation, apply to IHAs as for any other medical exposure.

The balance for benefit verses detriment when justifying exposures for IHAs may not be as clearly defined as for other exposures and may be based on risk factors rather than symptoms.

In 2007 Committee on Medical Aspects of Radiation in the Environment (COMARE) published a report on 'personally initiated CT scanning for health assessment of asymptomatic patients.'⁴² The report made several recommendations, one of which was that services offering whole body CT scanning assessments stop immediately as there is little evidence that the benefit outweighs detriment.⁴³

Regulation 7(7)(c) requires that practitioners and operators should pay special attention when optimising health-screening programmes. Special attention has not been defined in law, however, an example of special attention for justification may be that it is always a consultant radiologist who justifies these exposures rather than a radiographer. It is unlikely the processes of optimisation will differ from the standard requirements of the regulations which include justification, dose awareness, staff training and competence, equipment performance and so on.

Health screening scenario

On a three-year cycle, an invitation to attend for a screening mammogram is offered to women within an age range as described by the National Breast Screening Programme. Non-statutory guidance says that there is no requirement to have a named referrer for an individual who has a medical exposure as part of a national screening programme. Set referral criteria are checked with the individual by a healthcare professional. The questions asked include age, previous mammography imaging, any current symptoms and so on. This ensures the exposures are appropriately justified and will exclude individuals where an alternative care pathway should be followed.

Independent health assessment scenarios

A 38-year-old female is concerned that she may have colon cancer as this has been diagnosed in a close relative. She enquires about the possibility of having a CT scan at an IHA CT scanning service, for peace of mind.

She is asked to complete a comprehensive health questionnaire which is reviewed by a consultant radiologist. The radiologist will use the information provided to assess individual risk factors and, where appropriate, to justify an examination.

A 60-year-old male who is a smoker with a strong family history of coronary artery disease but no medical symptoms, enquires about the possibility of having a cardiac CT scan at an IHA CT scanning service.

An extensive health questionnaire is completed, reviewed and justified. The individual has a calcium score CT scan examination.

14. Occupational health surveillance

Occupational health surveillance is defined in Regulation 2 as 'medical surveillance for workers.' The regulations apply to any individual undergoing a medical exposure as part of health surveillance which may be required for their work. Examples are commercial pilots, divers and miners. The responsibilities associated with the roles of referrer, practitioner and operator apply.

Since IR(ME)R came into force there is less reliance on routine medical exposures to determine fitness to undertake certain occupations.

Military personnel, oil rig workers and air crew

These groups of employees may be required to undergo dental radiography. Imaging may be used to detect any pre-existing dental disease which can be treated pre-emptively to reduce the likelihood of an expensive repatriation if symptoms develop while in a remote location.

Divers and other workers using compressed air

In most circumstances, a routine chest X-ray is no longer required as part of an initial medical

assessment. They should only be undertaken if justified based on clinical judgement, taking into account medical history and results of the medical examination. However, submarine escape trainees may still require a routine posterior to anterior (PA) chest X-ray as part of their initial medical assessment.

Guidance is available relating to medical assessments for these workers, including information on when imaging is appropriate. This can be found on the Health and Safety Executive (HSE) website.⁴⁴

Mining and other quarry workers

The HSE has provided advice for occupational health professionals for this cohort of workers. The healthcare professionals involved in each surveillance programme may develop the scheme for their workers as appropriate.

When health surveillance is deemed necessary, a healthcare professional will refer and justify imaging with prescribed time frames.

15. Medico-legal exposures

A medico-legal exposure is defined in Regulation 2 as a 'procedure performed for insurance or legal purposes without a medical indication,' for example, those related to legal proceedings or those for emigration purposes.

The regulations have a number of requirements that must be met in addition to those that apply to any medical exposure. These specific requirements are described in Regulations 6(3)(a) and 7(7)(a).

The requirements are that:

- The practitioner must pay special attention when justifying medico-legal referrals
- The practitioner and operator must pay special attention to the need to keep doses arising from medico-legal exposures as low as reasonably practicable.

Special attention has not been defined in law, however, an example of special attention for justification may be that it is always a practitioner that justifies these exposures rather than an operator using authorisation guidelines.⁴⁵

The employer is required to have in place a written procedure regarding medical exposures for medico-legal purposes (Schedule 1[c]). Table 8 lists the requirements for medico-legal exposures under the regulations and gives some examples of how the written procedure could describe implementation of these.

Table 8. IR(ME)R requirements for medico-legal exposures

Requirement	Things to consider
Special attention when justifying the exposure	Could all medico-legal exposures be justified by a radiologist?
Special attention when optimising the exposure	A description of any additional optimisation that may be put in place, for example, reduced number of views.

Consideration could also be given to including a description of how medico-legal exposures may be identified.

A letter from a solicitor is sent to the imaging department requesting a cervical spine X-ray on a patient who is claiming to have suffered whiplash following a car crash. The letter is reviewed by a radiologist who then arranges for the appropriate examination to be undertaken.

In this scenario, while it is the solicitor that has requested the medical exposure, they cannot be the referrer under IR(ME)R as they are not a registered healthcare professional. The radiologist who receives the letter should complete a referral for the appropriate

examination and will, therefore, be the referrer for this medico-legal exposure. An example of special attention may be that all medical exposures for insurance purposes are justified by a consultant radiologist.

Emigration chest X-rays

Many countries require individuals to undergo chest radiography as part of the visa application process. These exposures are medico-legal exposures.

In practice, the majority of these X-rays are undertaken in a very limited number of departments as many countries only accept images from a specified list of providers.

Imaging for suspected drug smuggling

These examinations are medico-legal exposures when the individual has no clinical symptoms.

A request for a CT scan of the abdomen and pelvis of an individual suspected of swallowing packages containing drugs arrives in the radiology department. The request is directed to a consultant radiologist who checks the referral complies with an agreed protocol and acts as referrer and practitioner for this examination.

The radiographer performing the examination completes the ID and pregnancy checks (if appropriate) in accordance with departmental standard procedures. The procedure is explained and the individual signs a form consenting to the examination. The appropriate optimised CT protocol is selected to ensure the lowest dose for the required image quality. The scan is performed and a clinical evaluation of the images is made.

The referral may have come from the Customs and Excise service but it is the consultant radiologist who acts as the referrer and practitioner for the examination. Although

consent is not part of IR(ME)R, the radiographer ensures that the individual is aware of the reason for the examination.

16. Paediatrics

Regulation 7 (7)(b) states that the practitioner and operator shall pay special attention when optimising medical exposures for children.

Special attention has not been defined in law, however, an example of special attention when optimising exposures for children may be, for example, the use of specific X-ray rooms in a department where children are imaged. This decision may be made taking into account exposure optimisation for paediatrics affecting dose or perhaps a more child friendly environment.

Regulation 6 (2)(a) describes how all medical exposures must be justified to take into account the net benefit. It also says that the specific question to be answered and the characteristics of the individual must be taken into consideration. For paediatric exposures, this could be demonstrated by the use of ultrasound as a primary imaging modality to answer the clinical question of abdominal pain, for example.

When justifying referrals, the guidelines used for adults may not necessarily be appropriate for children. If guidelines are used to assist the justification and authorisation process they

- The investigation of developmental hip dysplasia or non-accidental injury (NAI) in a baby (specific only to children).
- Imaging of the chest for suspected infection – there are fewer indications for initial imaging and follow-up in the younger patient (due to the different course and pattern of risk for the younger patient with chest infections).
- Then investigating abdominal pain in a child, ultrasound is commonly the first examination employed (this demonstrates the 'special attention' applied when justifying the referral).

While patient anxiety, fear, lack of co-operation and inability to keep still are not exclusive to childhood, the likelihood of practical difficulties in obtaining a radiological examination are much greater with children.⁴⁶

Experience and expertise are required when imaging the young.⁴⁷ Good radiographic

should be child specific and special care should be taken to identify the child patient.

The regulations define a child as person under the age of eighteen in England and Wales or under the age of sixteen in Scotland.

Under IR(ME)R the processes of referral, justification, optimisation and evaluation are the same for children as for adults as are the roles and responsibilities of the employer, referrer, practitioner and operator. However, special consideration and attention should be applied to child patients for a number of reasons.

Children carry a greater risk of radiation induced injury than adults, especially for younger children and girls. The effect of radiation upon the rapidly growing and dividing cells of the young child is heightened. This increased risk must be accounted for when considering detriment versus benefit.

The specific disorders and diseases of childhood are not necessarily managed in the same way as an adult patient. There are some examples below.

technique, for example correct collimation (rather than post-process image cropping), centring on the region of interest, use and development of paediatric exposure charts (age and size specific) and protocols are key to safe and appropriate imaging of children.

Suspected non-accidental injury (NAI)

An 18-month-old child attends the X-ray department for a chest X-ray for a suspected chest infection. While reporting the image, the radiologist notices a number of healing rib fractures. The radiologist discusses the case with the clinician treating the child who then contacts a paediatric specialist. This specialist refers the child for a NAI skeletal survey.

In this scenario, the original referral for the chest X-ray is not a medico-legal exposure as it was performed for clinical reasons. The fact that the image may be used at a later date as evidence in legal proceedings is irrelevant. However, the

subsequent skeletal survey would be considered as a medico-legal exposure.⁴⁸ A comprehensive NAI protocol should be carried out to ensure a full and appropriate imaging record is completed.

17. High-dose examinations

It is a requirement of IR(ME)R that special attention is paid to medical exposures involving high doses to the patient (Regulation 7[7][d]) which may include CT, fluoroscopic and interventional procedures. Some aspects of this special attention should arise through an appreciation of the higher dose levels in these modalities, combined with the required processes of justification and optimisation, and the procedures for pregnancy and so on described elsewhere in this document.

However, specific additional considerations are required where individual organ doses could approach, or be up to, a few Grays (Gy) of radiation, as can occur, for example, in certain interventional cardiology and CT procedures. Such doses can exceed the minimum threshold for tissue reactions including hair loss, skin erythema, more severe skin effects, cataracts and induction of cardiovascular disease.

Departments where these procedures are conducted should have in place a procedure 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 a DAP value for the relevant examination type and/or on the cumulative dose at a reference point, a value which is usually displayed on the imaging equipment. Facilities for dose mapping that will significantly improve the ability to identify such cases may be available on new equipment. There are also some emerging technologies that allow the storing of such dose maps, and this information could be of use in those high-dose procedures that are staged. The departmental procedure should include a process for the clinical follow-up of relevant cases. Departments should also consider specifically including radiation effects within the process of obtaining informed consent for relevant types of procedure.

Staff should be aware that high dose levels similar to those mentioned above can also be delivered in CT-fluoroscopy procedures. Given the high power of modern CT X-ray tubes, dose levels approaching deterministic thresholds can be reached very rapidly, on the time scale of a minute or less.

18. Document control and audit

Procedures and protocols

In all good 'systems' an element of management oversight is required to both provide upward assurance regarding performance to those who take ultimate 'employer' liability and also to ensure that, at the department level, performance is maintained for operational reasons. Such oversight may have many facets, however, one of these is ensuring that documentation is up to date, used by staff, reflects staff and external feedback and that only a single version is in circulation. This requires a formal document issue and control system, although the level of formality is to be determined locally depending upon the complexities of the IR(ME)R system and the culture of the department. In developing such control locally the following should be addressed.

- How are new or revised procedures signed off? Who should be expected to do so?
 - Who should issue IR(ME)R employers procedures? Where are they kept so that staff may access them? (Paper versus electronic documents/access)
 - Regarding protocols or standard operating procedures (SOPs), how are these authorised?

How are procedures and protocols reviewed?

The management of procedures should ensure that only the latest version of any document is used by staff when undertaking their activities. For procedures this is most easily accomplished via electronic shared areas on hospital servers that all staff have 'read only' access to. In this case, printing should be discouraged as it increases the probability of outdated paper copies existing in offices and shared working areas. However, with appropriate control, paper copies are also acceptable and the choice will depend upon resources and culture at a local level.

The sound management of protocols is essential to ensure patients are exposed using correct radiographic factors and techniques. This is fairly straight forward in plain radiography modalities where printed exposure charts are used. However, when the technique is wholly or partly embedded in the modality computer control system (such as interventional or CT) then a robust process is required to ensure these protocols remain well controlled. There have been many instances of software updates or reloads that have changed modality preset values for scanning. A system should be in place to ensure that such settings have not been changed following service or repair.

Quality assurance relating to IR(ME)R

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

Regulation 2 of IR(ME)R defines QA as 'any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and safely complying with agreed standards and includes quality control.'

'Quality control' means the set of operations (programming, coordinating, implementing) intended to maintain or

to improve quality and includes monitoring, evaluation and maintenance at required levels of performance.

The required QA programme should cover all aspects of the diagnostic imaging process. To ensure that the QA programme is being followed, a system of regular audit is essential.

This is a different programme to that required under IRR99 where X-ray equipment and facilities undergo regular testing for compliance against a set of standards on a regular schedule.⁴⁹

A schedule of audit may be drawn up on a rolling programme to check employer procedures are in place and being followed.

Some examples of audits are included below; this list is not exhaustive.

- IR(ME)R operator/practitioner entitlement is up to date and accurate
- Operator training records are available and up to date
- DRLs have been reviewed as per the employer's procedure, doses are accurately recorded and action taken where DRLs are consistently exceeded
- Patient ID procedure: is it possible to identify who performed the ID check and are they entitled to do so?
- Justification and authorisation: is it possible to identify the practitioner for a sample of examinations?
- Clinical evaluation: is there evidence of a written clinical evaluation in a sample of patient records for medical exposures that were evaluated by non-radiology staff?

Employer's procedures are usually reviewed on a regular basis, for example, every three years.

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

Regulation 4(1) requires the employer to have written procedures for medical exposures, one of which is 'procedures to ensure that quality assurance programmes are followed,' (Schedule 1[e]). Therefore, in the context of IR(ME)R, a QA programme is an organised effort that delivers the standards of patient exposure as described in the organisation's IR(ME)R procedural framework. IR(ME)R requires that this organised effort is described and this effort should form part of the whole IR(ME)R system. This wider system should include not just core IR(ME)R procedures listed in the regulations but also the control mechanisms such as control of documentation and how the system is audited. This is achieved by conducting quality control checks. The IR(ME)R requirement for QA of procedures comprises the aspects described above – proper control of procedures and checking that they are adhered to.

19. Inspection and reporting of incidents

Incidents

Under Regulation 4(5), the employer is required by IR(ME)R to report ‘..that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended.’

To do this ‘he shall make a preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt

that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received,’ (Regulation 4[5]).

To ascertain if an incident is reportable, a local investigation needs to be carried out at the earliest opportunity following the incident. This investigation should include details of what happened, where it happened and when, the staff involved and reasons why the incident occurred.

A radiographer realises after performing a CT scan that they have carried out an examination on the wrong patient. They inform their manager about the incident. The radiographer also completes an incident report. The manager, with input from the MPE, undertakes an investigation to determine what happened and whether it is reportable to the IR(ME)R inspectors. The manager speaks to the staff involved to gather all relevant information. The MPE undertakes a dose estimate and calculates the risk to the individual from the unintended exposure.

Following a discussion between the referrer and the investigation team, a decision is made with regard to informing the patient. The scan is reported and saved against the correct patient record with a note about the incident having occurred – any unexpected findings are communicated to the appropriate clinician.

In most cases where an incident has occurred and this is identified at the time an apology should be given to the patient. When patients are informed of errors and explanations of risks are given it is advisable to consider risks in broad categories.^{50,51} Organisations may need to consider appropriate training of radiographic staff and it may be helpful to develop supporting documents to aid this process (such as a leaflet). Where incidents are identified at a later date and the risk is small, consideration should be given to whether informing the patient may cause unnecessary distress.

Organisations should develop local policies for this and it is hoped there will be more detailed guidance produced by the professional bodies in the future.

IR(ME)R is enforced by different organisations within each of the four home nations. These are known within the regulations as the ‘appropriate authorities’. They are as follows:

- England – The Care Quality Commission (CQC)⁵²
- Northern Ireland – The Regulation and Quality Improvement Authority (RQIA)⁵³
- Scotland – The Scottish Ministers⁵⁴
- Wales – Healthcare Inspectorate Wales (HIW)^{55,56}

The Department of Health IR(ME)R ‘Notes on Good Practice’ further clarify when to report by adding the following statement, ‘Patients who undergo a procedure that was not intended, as a result of mistaken identification or other procedural failure, and consequently have been exposed to an ionising radiation dose, should be

considered as having received an unintended dose of radiation.⁶

Ideally, all near miss incidents should follow the same pathway as an incident so that lessons learnt can be applied and have the potential to prevent an actual incident from occurring. The process of investigation of incidents and near misses, including responsibilities and timescales, may be laid out within employer's written procedure to standardise the process of investigation, although this is not required under legislation.

Incidents involving equipment malfunctions are reportable to the HSE.⁵⁷

Inspections

Inspections may either be proactive, as part of an inspection programme, or reactive in response to an incident or anonymous 'whistle blower'. Inspectors may request, in advance, copies of procedures and records. In planning for a proactive inspection if notice is given, the organisation would be advised to ensure all relevant personnel are available to answer the inspectors' questions so that all required answers are immediately forthcoming – this reduces the need for sending on records and responses post-inspection. It should be noted that inspections can be unannounced.

The inspectors will carry identity badges and documentation and will have been appointed for purposes including the collection of evidence which may be used for enforcement purposes and for making enquiries relating to compliance with the regulations. Before any inspection, relevant staff should be briefed to ensure they provide the required information to aid the inspectors.

During an inspection, inspectors may ask for access to any person within the organisation and any document relevant to their line of enquiry. At the end of the inspection, representatives of the host organisation will usually be given feedback and the opportunity to ask questions of the inspectors. Following such an inspection, the inspectors will generate a draft report of their findings that the organisation may comment on for matters of accuracy. The final report will be issued and may be made available on the inspectorate's website. The results will be shared with the host employer.

The findings of an inspection may also lead to enforcement action by the inspectorate to remedy any shortcomings in practice that are found. These enforcement actions may include criminal proceedings against the employer and/or individuals with responsibility under IR(ME)R, namely referrers, practitioners and operators. However, it is more commonly seen that an improvement notice will be served for regulation breaches against the employer.

The regulations in Great Britain are enforced under section 15 of the Health and Safety at Work Act 1974. In Northern Ireland they are enforced under Article 17 of the Health and Safety at Work (Northern Ireland) Order 1978.^{4,5}

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Approved by the British Institute of Radiology: 27 February 2015

Approved by The Royal College of Radiologists Clinical Radiology Faculty Board: 27 February 2015

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Appendix 1. IR(ME)R schedule 1 procedures¹

The written procedures for medical exposures shall include:

- a. Procedures to identify correctly the individual to be exposed to ionising radiation;
- b. Procedures to identify individuals entitled to act as referrer or practitioner or operator;
- c. Procedures to be observed in the case of medico-legal exposures;
- d. Procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;
- e. Procedures to ensure that quality assurance programmes are followed;
- f. Procedures for the assessment of patient dose and administered activity;
- g. Procedures for the use of diagnostic reference levels established by the employer for radio diagnostic examinations ... Specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;
- h. Procedures for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 7(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(d) where no direct benefit for the individual is expected from the exposure;
- i. Procedures for the giving of information and written instructions as referred to in regulation 7(5);
- j. Procedures for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose;
- k. Procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

Appendix 2. Things to consider when writing employer's procedures

Things to consider when writing employers' IR(ME)R procedures; this list is not exhaustive.

1. ID procedure

- Who is responsible for carrying out ID checks? Is it the person undertaking the exposure?
- When does the ID check happen?
- How is this completed? Ask active questions? Check hospital identification wrist band if available?
- Consider language barriers/age/mental capacity/inpatients/theatre and unconscious patients
- What if there is more than one operator involved in the examination, for example, two radiographers in CT or a cardiologist and radiographer in the catheter labs?

2. Entitlement of duty holders

- Describe how the employer is made aware of their responsibilities under IR(ME)R
- Describe how the task of entitlement is delegated by the employer
- Describe how entitlement takes place and by who
- Describe how competence is assessed and by who
- Outline how the scopes of practice are reviewed, for example, annual appraisal
- Clarify who holds the training records.

3. Medico-legal exposures

- What medico-legal exposures are undertaken?
- Describe the special attention for justification
- Describe the special attention for optimisation.

4. Enquiries for females of child bearing age

- Who is responsible for checking pregnancy status? Is it the person undertaking the exposure?
- What is the age range? Explanation of when 10/28 day rule applies
- Use of a flow chart may be helpful
- Describe what happens if more than one operator is involved in the examination, for example, two radiographers in CT or a radiologist and radiographer in fluoroscopy
- When is pregnancy checking required? When and where might this check happen?
- How is this completed? Is it documented? Where is it documented?
- Consider language barriers/age/mental capacity/inpatients/theatre and unconscious patients
- If a female is unsure or says that she is pregnant, what happens?
- How is the exposure justified if unsure or pregnant, for example, is this justification completed by a radiologist?
- How are projections or examinations limited to reduce the dose to the fetus?
- Reference local child safeguarding procedures and contact details for support for staff.

5. Quality assurance procedure

- Outline the document control required for IR(ME)R documentation
- How often will the procedures/protocols be reviewed? Every three years?
- What if practice changes between these times?
- Include:
 - Version number
 - Author
 - Authorised by
 - Issue date
 - Review date
 - Page no.

6. Assessment of patient dose

- How is dose recorded?
- Consider what dose information is recorded for all modalities. What units are recorded?
- Who carries documents regarding the dose information? Consider areas away from radiology
- How is this information made available to staff?
- How often is it reviewed?

7. Diagnostic reference levels (DRLs)

- What DRLs are in place? Local, national, paediatric?
- Are they on display or included within the exposure chart?
- How often are they reviewed and by who?
- How would you know if they were being consistently exceeded?
- What actions should be taken by the staff and the employer if they are being consistently exceeded?
- Procedure should state that DRLs are not expected to be exceeded when good and normal practice is applied.

8. Research

- Dose constraints – when no direct medical benefit is expected to the individual from the exposure
- Target doses – for patients who are expected to receive a diagnostic or therapeutic benefit from the exposure
- Special attention for justification
- Consider volunteers
- Volunteers/patients must be informed of risk regarding radiation in advance – how is this achieved?

9. Clinical evaluation and patient dose

- How is clinical evaluation recorded? Where is it recorded – on RIS or PACS, in the patient's notes?
- Who records the clinical evaluation? Consider evaluations that take place outside the radiology department, for example, orthopaedic clinic, intensive therapy unit (ITU)
- The operator carrying out this task should be identifiable and entitled in the employers procedures
- What should the evaluation contain?
- Describe the process in place for unexpected findings.

10. Reducing the probability and magnitude of accidental or unintended exposure

- Employer's procedures and protocols should be in place and regularly reviewed by the author to ensure they reflect local practice
- All equipment should regularly undergo QA by operators and medical physicists to ensure it is functioning correctly
- Additional equipment QA checks should be carried out by radiographers if over 10% of images are deemed unacceptable
- How is feedback shared with staff following incidents?
- Training and competence assessments should be undertaken, including when new equipment and procedures are introduced
- Induction programmes for new staff
- Clinical audit including audit of procedures
- Application of good practice and technique
- Investigation of near miss incidents – demonstrate learning from incidents
- Peer review of images – looking at image quality to include positioning, collimation etc.

11. Referral

- How is a referral made? Is this electronic, written request form or letter?
- Clarify what referral criteria are made available to referrers and who is responsible for ensuring availability.

12. Justification and authorisation

- Describe how authorisation is carried out? Demonstrated by writing on request form (where) or electronically?
- How is the duty holder identified?
- Is this a standardised approach?
- Are there authorisation guidelines issued by a practitioner for operators to authorise against? Consider – are the duty holder's roles clearly defined in the guidelines?

13. Incident reporting

- What is reported? Are all incidents including 'near misses' recorded?
- Who is responsible for reporting the incident? Describe the process to be followed
- Involve the MPE/radiology practitioner assistance (RPA)
- Who is involved and carries out the investigation?
- When is external reporting necessary?
- How is feedback delivered to staff?
- Include timescales for reporting and investigating.

14. Audit

- What audits are regularly completed? Describe the process?
- How often are they completed?
- Describe how the results are used.

15. Training

- Outline the approach taken to training and education
- Describe the induction process
- Clarify who holds training records
- Describe when and how scopes of practice are reviewed
- Clarify the situation for students, trainees and third party employees.

Appendix 3. Example scope of entitlement

Competencies for entitlement as a duty holder under IR(ME)R at hospital

Name of duty holder:	Job title:
Qualification(s) and date obtained:	
Registration number:	
Training records held by:	

Referrer functions at hospital	Assigned as competent
	Date and signature/initials of duty holder and assessor
Refer for all X-ray examinations	
Refer for all general X-ray examinations	
Refer for all CT examinations	
Refer for interventional radiology procedures	
Refer for mammography	
Refer for DXA	
Refer for barium studies	

Practitioner functions at.....hospital	In training Date and signature/initials of duty holder and assessor	Assigned as competent Date and signature/initials of duty holder and assessor
Competent to justify requests for all X-ray examinations		
Competent to justify requests for all general X-ray examinations		
Competent to justify requests for all CT examinations		
Competent to justify requests for all interventional radiology procedures		
Competent to justify requests for mammography		
Competent to justify requests for DXA		
Competent to justify requests for barium studies		

Operator functions at XXXXX hospital	In training Date and signature/initials of duty holder and assessor	Assigned as competent Date and signature/initials of duty holder and assessor
Competent to carry out patient identification		
Competent to carry out pregnancy enquiries		
Competent to authorise against general X-ray guidelines		
Competent to undertake all general X-ray examinations in Rooms 1, 2 and 3		
Competent to undertake CT in CT1		
Competent to undertake CT in CT2		
Competent to use the equipment for interventional examinations in Room 4		
Competent to undertake mammography		
Competent to undertake DXA		
Competent to undertake barium studies		
Competent to process CR plates		
Competent to clinically evaluate general X-ray examinations		
Competent to clinically evaluate CT examinations		
Competent to clinically evaluate interventional procedures		
Competent to clinically evaluate mammography		
Competent to clinically evaluate DXA		
Competent to clinically evaluate barium studies		
Competent to clinically evaluate orbits pre MRI		
Competent to carry out quality assurance on equipment		

Entitled by:	Date:
Name of entitler:	Date:
Signature of duty holder:	Date:
IR(ME)R procedures read by duty holder:	Date:

Competencies for entitlement as duty holder under IR(ME)R at breast imaging unit.....hospital NHS trust mobile units within thetrust

Name of duty holder:..... Job title:.....

Qualification(s) and date obtained:

Training records held by:

Operator functions at breast imaging unithospital NHS trust and mobile screening units	In training Date/signature/initials of duty holder and assessor	Assigned as competent Date/signature/initials of duty holder and assessor
Competent to verify patient identification		
Competent to authorise against authorisation guidelines		
Competent to undertake standard 2 view screening mammography		

Operator function at breast imaging unithospital NHS trust	In training Date/signature/initials of duty holder and assessor	Assigned as competent Date/signature/initials of duty holder and assessor
Competent to undertake non-standard screening (eg. implants, further views) Room 1 breast imaging unit Room 2 breast imaging unit		
Competent to operate Room 2 for stereotactic breast biopsy procedures		
Competent to undertake mammography – core biopsy in Room 1 breast imaging unit Room 2 breast imaging unit		
Competent to undertake quality assurance tests on all mammography equipment. static and mobile		
Competent to use NBSS breast screening information system		
Competent to use Trust RIS/PACS		

Entitled by (print name)

Signature of entitler: Date:

Signature of duty holder: Date:

IR(ME)R procedures read by duty holder

Signature Date: Date:

Appendix 4. Example of a local training record

Name			Document No.	TR 1
Job title	eg. Radiographer			
Site/room/equipment	eg. Royal Hospital, Room 1, DR X-ray machine DX321			
Task	✓	Trainer initials	Trainee initials	Date
Switch radiographic equipment on and off including isolator switches				
Select patient from work list				
Aware of exposure charts and protocols				
Add additional projections to pre-set programme				
Amend exposure factors				
Collimate accurately and appropriately				
Knowledge of internal filtration				
Knowledge of available external filtration/silicon wedges				
Adjust contrast and brightness of image				
Rotate image				
Annotate image				
Crop image appropriately				
Carry out all general X-rays as per protocol				
Record exposure factors/dose following exposures				
Send image to PACS				
Carry out QA on equipment				
Location of 'Out of Order' sign				
This person has been trained and deemed competent on the above tasks			Date	
Signature of trainer:				
Name of trainer:				
Signature of duty holder:				

Appendix 5. Example of authorisation guidelines

Breast screening service authorisation guidelines breast imaging unit hospital trust

Every woman that attends the unit for breast screening must be checked to see if they meet the requirements of the NHSBSP and the breast imaging unit at hospital trust before a mammogram can be performed.

Breast screening may be authorised if:

- The woman is aged between 47–73 years
- Six months have elapsed since previous mammogram
- The client has not undergone bi-lateral mastectomy.

Exceptional circumstances when breast screening mammography may be authorised:

- Women attending on wrong day without invitation letter
 - A mammogram should only be performed once the radiographer/AP contacts the screening office and verifies the client is registered with the screening unit and fulfils the above criteria 1–3 for breast screening mammography.
- Women, who have been previously invited but did not attend and now attend opportunistically
 - A mammogram must only be performed once the radiographer/AP contacts screening office and verifies the client is registered with the screening unit and fulfils the above criteria 1–3 for breast screening mammography.
- Women over current age range
 - Women over the current age range can self-refer as they remain eligible for screening once every three years.

Breast implants

All breast implant clients must currently be imaged at the breast imaging unit. The protocol and exposure factors for breast implants are in each mammography room behind the control panel.

Employer's procedures – authorisation guidelines

Author: Dr A Jones, Breast screening lead consultant radiologist

Signed:..... Date:

Version: 1.0

Review date:

Appendix 6. Example of group entitlement

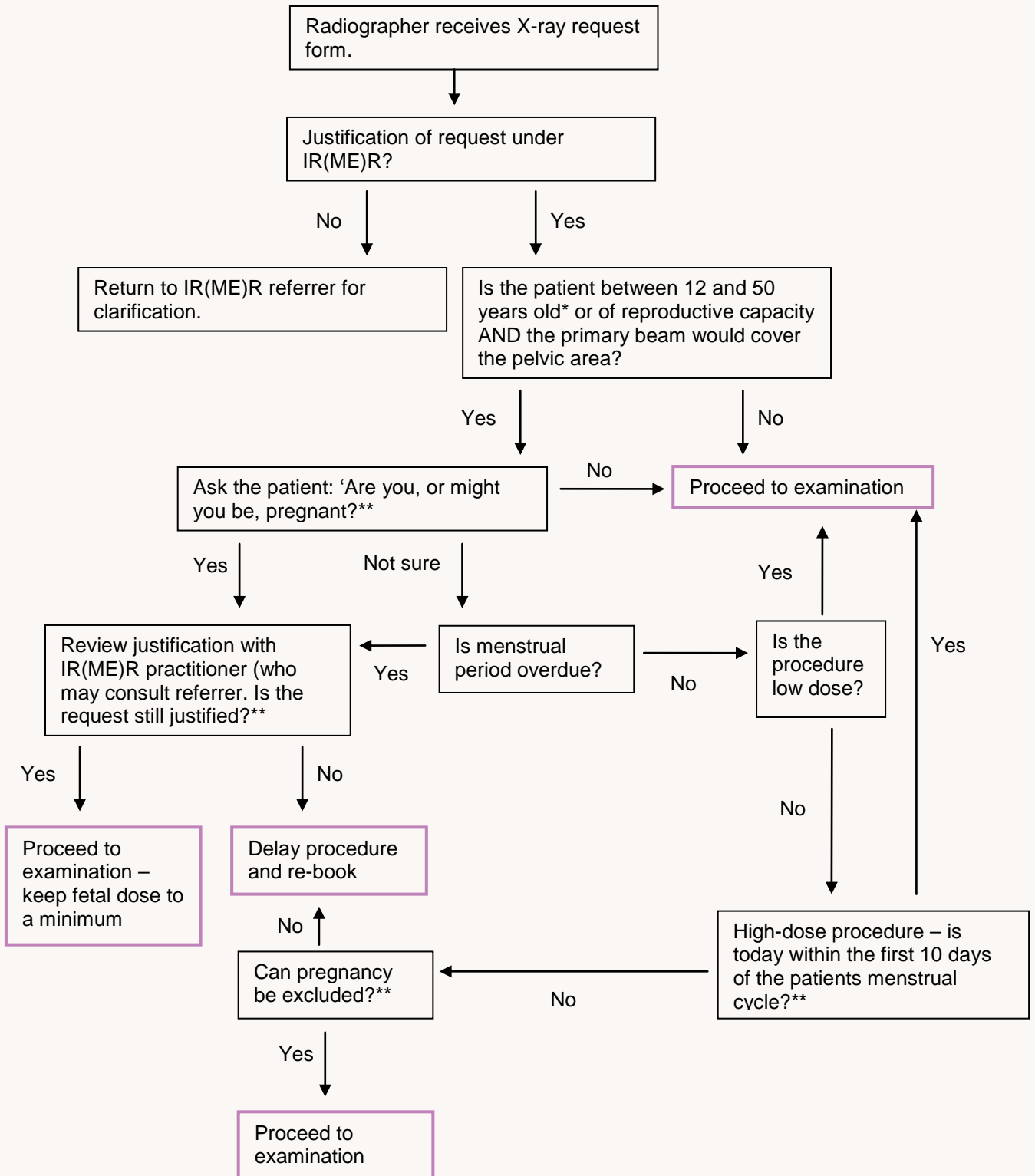
Referrers

Staff group	Registration	Scope of referral
Medical consultant	GMC registration	Diagnostic examinations Interventional examinations within specialty
Non-consultant hospital doctor	GMC registration	Diagnostic examinations
General practitioners	GMC registration	Diagnostic examinations (excluding CT)
Dental practitioners	GDC registration	General radiography and CBCT of the jaw and CXR for inhaled foreign body.
Radiographers	HCPC registration	Orbits X-ray – foreign body identification for MRI
Ultrasonographers	HCPC registration	Abdominal X-rays
Emergency nurse practitioners	NMC registration	Extremity radiography of patients >5 years
Physiotherapists	HCPC registration	General radiography of extremities and spine
Speech therapists	HCPC registration	Video fluoroscopy

Practitioners

Staff group	Registration and training	Scope of justification
Consultant radiologists	FRCR and GMC registration	Diagnostic examinations Interventional examinations
ARSAC certificate holders	GMC registration plus training approved by ARSAC committee	NM diagnostic, therapeutic and research procedures listed in personal ARSAC certificate
Dental practitioners	Dental degree and GDC registration	General radiography of the jaw
Cardiologists	Membership of RCP and GMC registration	All cardiology procedures
Radiographers	HCPC registration and completion of in-house training programme	All general radiography
Speech therapists	HCPC registration and completion of in-house training programme	Video fluoroscopy

Appendix 7. Pregnancy flowchart



*age range by local agreement and reviewed regularly

**record patient response in line with employer's procedure

Citation details

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