Communicating Radiation Benefit and Risk Information to Individuals Under the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)

ISBN: 978-1-911738-12-1 March 2025



207 Providence Square Mill Street, London SE1 2EW, UK 020 7740 7200 info@sor.org

www.sor.org

Disclaimer

The Society of Radiographers <u>(SoR)</u> and the College of Radiographers <u>(CoR)</u> are separate companies (CoR is also a registered charity) but work together as the Society and College of Radiographers ("SoR" and the "CoR") and as part of their roles prepare and publish guidance.

All guidance published by the SoR and/or the CoR is for the purpose of assisting members, professionals, patients and the general public and sets out what the SoR and the CoR consider to be recommended practice. While the intention of the guidance published is to set out best practice and to influence practices across the sector, any local procedures implemented by local NHS trusts, health boards, independent providers (or other employing authorities) will always take precedence. The SoR and the CoR have no role in enforcing the application of any guidance.

The rights and benefits of members of the SoR are set out in the SoR Handbook.

© The Society and College of Radiographers 2025. Material may only be reproduced from this publication with clear acknowledgement that it is the original source.

Contents

1	Executive summary		4
	1.1	Background	4
	1.2	Purpose of guidance	5
2	Guidance		7
	2.1	Overview	7
	2.2	Duty holders	9
		2.2.1 Entitlement	9
		2.2.2 Training	10
	2.3	Practical advice for communicating radiation risks	11
	2.4	Carers and comforters	14
	2.5	Typical patient scenarios	14
	2.6	Communicating benefit and risk in radiotherapy	18
3	Summary		21
	Appendix 1		22
	Comparison of doses from sources of exposure		22
	References		23

1. Executive summary

This update considers the impact of The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024¹ which came into effect in England, Wales and Scotland on 1 October 2024, and reflects practice changes since 2019.

The Ionising Radiation (Medical Exposure) Regulations 2017², and The Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2018³ came into force on 6 February 2018 in accordance with the European Council Directive 2013/59/Euratom⁴. The Society of Radiographers (SoR) and the College of Radiographers (CoR) consider this a timely opportunity for employers (and radiography departments) to re-evaluate governance processes around the regulatory framework, in particular the Schedule 2 (i) requirement for employer's written procedures for exposures to include procedures "providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure"^{2,3}.

This information should include the benefits of the exposure and, where appropriate, the lifetime risk of developing cancer, the limitations of the proposed radiological/radiotherapy procedure(s) and the potential consequences of not making diagnoses or delivering treatment. Information should be available in a variety of forms to meet the needs of a diverse population.

1.1 Background

4

Both the Great Britain^{1,2} and Northern Ireland³ regulations have the same requirement relating to communicating benefit and risk, therefore throughout this document they will be jointly referred to as IR(ME)R.

IR(ME)R identifies four duty holders, each of whom has clearly identified responsibilities under the regulations: the Employer, Referrer, Practitioner and Operator. For the purpose of clarity in this document, these duty holders are represented by capitalised words in order to distinguish this role from an individual's job title.

The European Council Directive 2013/59/Euratom (Article 57 (1) (d))⁴, stipulates that the responsibility to give "adequate information" lies with the Referrer or Practitioner as specified by member states. IR(ME)R does not include this in Regulation 10: Duties of the practitioner, operator and referrer; instead it is included in Schedule 2 (i) Employer's Procedures, although it is not specified who should give this information. It is acknowledged that IR(ME)R Referrers and Practitioners should be sufficiently educated to communicate benefit and risk information to patients; however, the SoR and CoR firmly believe that normal UK radiological practice would mean that this task is likely to be delegated to the Operator. The Operator is normally a radiographer or an assistant practitioner (AP) but may be a radiologist, clinical oncologist, nuclear medicine (NM) physician, NM medical physics expert (MPE), clinical scientist, surgeon, nurse or other healthcare professional. In some cases an individual may act as IR(ME)R Referrer, Practitioner and Operator. In such case the task of providing adequate information will lie with the same individual.

Employer's procedures should clearly specify who (which duty holder) should be involved in providing benefit and risk information, and how this information should be communicated. This duty holder would therefore be required to ensure that a patient has received the required information, and that they understand it, before the exposure takes place. Risk communication is a core competency for all Practitioners and Operators (IR(ME)R Schedule 3 (1) (a)). Radiographers are required by The Health and Care Professions Council's *The standards of proficiency for radiographers*⁵ to "formulate and provide information and support for service users about their treatment and/or imaging process and procedures, with regular reappraisal of their information needs as appropriate".

*The Quality Standard for Imaging*⁶ Guidelines, Protocols and Clinical Safety (Standard XR-502: Consent) requires that "Communication of risk and benefit, including limitations and alternatives" is integral to consent procedures and that "All patients are supported in their decisions regarding consent for their imaging procedures". Standard XR-506: Imaging of Patients with Additional Requirements requires services to "demonstrate compliance with national and local guidelines for the imaging of patients with additional requirements through audit of the standard operating procedure (SOP)".

The requirements for communication of benefit and risk information apply equally to radiotherapy procedures and treatment.

The requirement of IR(ME)R Schedule 2 (i) provides another opportunity to put patients at the heart of radiation safety through local compliance assurance procedures.

1.2 Purpose of guidance

5

This guidance aims to provide clarity and support for the UK radiographic workforce to comply with IR(ME)R and help improve patient experience. There are a wide range of publicly available media resources offering advice about radiation dose and risk. Individuals may have preconceived ideas about ionising radiation, influenced by many sources, for example from television programmes, articles or blogs online or on social media, from friends and relatives, or from trying to work out

their potential dose/risk using a web-based tool or application. For some people it is empowering to research the evidence relating to their imaging investigation/treatment, but if they are unable to identify reliable and evidence-based information it can be distressing. It is argued that individuals judge the risk of an activity as lower when they understand its benefits⁷. Conversations with patients and service users about ionising radiation often focus on risks rather than benefits. As healthcare professionals it is our responsibility to consider the needs of the individual and to explain that for an examination/treatment to be appropriately justified, it has already been determined that the benefits to them (substantially in most cases) outweigh the lifetime risks associated with the exposure. Exceptions to this may be when what matters to the individual was not adequately considered, or the individual's choices or priorities have changed. If there is any doubt, it is the duty of the person undertaking the exposure to seek advice from the Practitioner to ensure it remains justified.

For example:

A patient is referred for a pre-operative knee x-ray by an orthopaedic surgeon who plans to undertake a knee replacement. The surgeon has explained to the patient that whilst surgery is likely to reduce the patient's pain it is unlikely to improve mobility and may reduce it further. The patient initially agrees to have the surgery. The referral is made and the examination is justified. The patient attends for the x-ray but during a conversation, prior to the exposure, the Operator learns that the patient has decided not to have the operation as mobility is more important to them than being pain free. In this case, has the balance of benefit and risk now changed? Is the examination still justified?

Although this guidance is primarily intended to support the radiographic workforce, the subject matter may also be useful for other healthcare professionals, for example medical and non-medical referrers, as awareness of radiation doses and associated risks in medical imaging is known to be low in some cases⁸. The more a workforce is prepared in terms of knowledge and understanding of radiation risks, the greater their confidence will be in delivering that information. This guidance supports existing practice for the benefit of the individual receiving the exposure and should not hinder already effective and safe practice. It is not intended to be prescriptive, but to act as an aide memoire to effectively support staff in the consistent delivery of relevant benefit and risk information prior to medical and non-medical imaging examinations. Practical scenarios that are colour coded for diagnostic (blue) and therapeutic (purple) practice are given.

2 Guidance

2.1 Overview

Anyone undertaking the communication of benefit and risk information to patients or other healthcare professionals should be adequately trained to do so. This is determined by the Employer, but should consider if a person has the theoretical knowledge and practical experience to:

- understand the clinical details including all medical terminology, abbreviations, and anatomical and physiological references
- understand the limitations of the procedure
- understand the dose delivered, diagnostic reference levels (DRLs), or dose reference levels (DRLs in radiotherapy)⁹, and dose constraints
- understand the benefits to the individual of the investigation/treatment and how it impacts on their future care
- understand the potential latent risks of the proposed exposure (the stochastic effects of later cancer induction — how long might it take for cell damage to become apparent?)
- understand the increased relative radiation risks when delivering exposures to paediatric patients (i.e. the greater radiosensitive nature of their organs)
- understand the known risks of the proposed exposure (the tissue/deterministic reaction, if there
 is any). Doses from clinical imaging examinations should not generally cause deterministic effects;
 however, particular care should be taken during image-guided interventional procedures where
 the risk of tissue damage may be greater. It is important the patient is alerted to this and
 understands the significance of any signs and symptoms including how they access aftercare
- understand the known risks of radiotherapy exposures for both planning and treatment, and have the knowledge and skills to continue benefit/risk conversations with patients after the consent process
- understand the clinical question for the proposed examination
- have good communication skills to listen to the needs of the individual knowing what matters to them

7

- comply with Schedule 2 (i) Employer's Procedures^{1–3} in delivering local patient information
- understand the potential risk to the individual of the investigation/treatment not being performed or completed
- understand the individual's fitness to consent to, tolerate, and comply with the procedure/ treatment
- make reasonable adjustments for those who need more time or additional resources to help them understand
- collaborate with the IR(ME)R Practitioner and MPE to ensure optimisation of the individual exposure, in accordance with the principle of 'as low as reasonably practicable' (ALARP), consistent with the intended purpose
- understand how benefit and risk may be different for:
 - » children
 - » carers and comforters (for therapeutic purposes this is only relevant to nuclear medicine)
 - » asymptomatic individuals (diagnostic only)
 - » individuals who may be pregnant or breastfeeding

People assimilate and process information in different ways. Some may consider radiation risk in a heuristic or critical manner and others may regard it as insignificant or an acceptable and necessary step on their healthcare journey. Similarly, the communication style chosen to deliver this information should be tailored to the individual receiving it, rather than assuming a generic 'one size fits all' approach.

It is important for patients and service users, and their representatives or carers to have trust in their relationship with the healthcare professional(s) delivering the radiation dose. It is argued that trust is more likely to influence how an individual judges benefit and risk when they lack knowledge of the risk. Whereas trust becomes unrelated to the judgement individuals make when they are more informed¹⁰. Patients and service users may be more likely to trust healthcare professionals if the information given correlates with that which they have discovered for themselves. If they understand the risk they are also more likely to perceive it as lower⁷. Without prior knowledge, individuals may have little concept of benefit and risk in the context of how to apply it to their personal circumstances.

Trust can be improved in a number of ways:

- competence through adequate training and ongoing education in the techniques and equipment in use
- compassion in conversations with patients listening to and understanding what matters to them
- confidence and capability to discuss radiation dose and risk in the context of the examination

Evidence suggests that IR(ME)R Referrers and Practitioners acknowledge their responsibility in providing patients and service users with this information but there is inconsistency in their ability to do so¹¹.

There is a well-documented gap between patient expectation and the delivery of information regarding the benefits and risks of ionising radiation exposure⁸.

2.2 Duty holders

It is imperative that all duty holders know who the **IR(ME)R Employer** is for their area of practice. They should recognise which duty holder role they undertake at each part of the patient journey. They must be fully aware of their tasks, responsibilities and limitations within each role and be aware of the relevant protocols, policies and procedures. The **IR(ME)R Operator** has responsibility for the practical aspects of a medical exposure; communicating information about ionising radiation benefits and risks before exposure is a practical task for which the individual should be adequately trained. It is important to clarify at this stage that the SoR and CoR firmly believe that the delivery of clear and concise information relating to radiation dose should form, where necessary, a fundamental but specific part of the consent process.

2.2.1 Entitlement

Duty holder entitlement is quite distinct from job title. Entitlement by the Employer should be given to each individual in writing and should be clearly annotated in the Employer's Procedures (IR(ME)R Schedule 2 (b)). The Employer may delegate the task of entitlement to another person, for example a radiology service manager. Each duty holder should have a scope of practice and be clear about what they are (and are not) entitled to do. The SoR and CoR consider those individuals entitled to act as IR(ME)R Operators should undertake regular reflection on their practice, to ensure they continue to meet the standards required for registrants and for their own professional development. The Employer should undertake regular audit of their written procedures for entitlement as part of a continuous quality assurance programme.

2.2.2 Training

Before entitlement is given, the Employer must ensure that IR(ME)R Operators have successfully completed training, including (as a minimum) theoretical knowledge and practical experience relevant to the Operator's particular functions and area of practice, as detailed in IR(ME)R Schedule 3. Areas of training need only reflect the tasks that the duty holder will undertake. The subject areas detailed in Table 1 of IR(ME)R Schedule 3 that are relevant to the IR(ME)R Operator's role should be covered in adequate breadth and depth so that the individual may function optimally in their role. Table 2 of IR(ME)R Schedule 3 details specific areas of knowledge and training relevant to specific areas of practice (diagnostic radiography, radiotherapy and nuclear medicine).

Successful completion of pre-registration radiography education and training approved by the College of Radiographers will provide evidence of adequate training as stipulated in IR(ME)R Regulation 17 (2). In addition to this, IR(ME)R Regulation 6 (3) (b) specifies a requirement for continuing education and training after qualification, particularly in relation to new techniques. This should form part of an ongoing continuing professional development (CPD) plan and relate to an individual's scope of practice.

IR(ME)R Regulation 14 is more specific in the need to involve an MPE, stating a requirement for the MPE to contribute to the optimisation of radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic and dose reference levels (DRLs) (IR(ME)R Regulation 14 (3) (a)). In house training programmes, study days, CPD, and Continuing Medical Education (CME) sessions are all opportunities to involve the MPE in raising awareness and improving the IR(ME)R Operator's optimisation skills and use of DRLs. This knowledge and the associated skills are necessary to ensure radiographers and assistant practitioners (APs) are competent and confident in their conversations with patients, and in their delivery of consistent benefit and risk information.

Patients may ask about the dose to be delivered during an examination or treatment and want to know how it compares with the 'average'. It is important that radiographers and APs provide consistent responses and have an awareness of local and national diagnostic reference levels and dose reference levels. UK Health Security Agency (UKHSA) have comparisons that explain why the millisievert unit (mSv) is used to measure radiation dose¹².

Insufficiently skilled practitioners or their inappropriate use of technology may contribute to an individual being at increased risk from medical or non-medical exposure⁸. Adequate information should assure service users of the governance processes in place for their safety. Training records should include the nature of the training and the date completed. This is especially pertinent as and

when new technologies are implemented. IR(ME)R Regulation 17 (4) requires the training records of all Practitioners and Operators engaged by the Employer for carrying out any exposures or any practical aspect of such exposures be available for inspection. It is important to note that this applies to both registered and non-registered healthcare staff and is irrespective of professional background.

2.3 Practical advice for communicating radiation risks

The use of a range of patient information materials (e.g. leaflets and posters in reception areas) is important, but ensuring individuals have the opportunity to ask healthcare professionals questions and receive clear explanations is perceived as being more ethical and transparent. Using published information (whatever the medium) as well as delivering verbal communication is better than using one single source of information. Effective communication is an integral part of the healthcare professional's role and dialogue should be tailored to the needs of the individual. It should be the case that patients and service users are equal partners in the design and delivery of patient information resources. This is in keeping with the NHS five year forward view¹³ and is reflected in the SoR and CoR strategies^{14,15} as well as the guidance document Patient Public and Practitioner Partnerships within Imaging and Radiotherapy: Guiding Principles¹⁶.

Standard XR-109: Patient, Carer and Service Partnerships is a key component of the Quality Standard for Imaging⁶ and requires services to demonstrate changes that have been made as a result of patient partnerships and the feedback received. It indicates that "The Service should focus more on coproduction than on seeking patient approval".

This guidance document aims to support staff in developing effective communication pathways. Communicating benefit and risk information effectively requires an understanding of what matters to the individual and should include information about the existence, nature, severity and acceptability of such risks and benefits. This is a fundamental principal of values-based practice in diagnostic and therapeutic radiography¹⁷.

It is important to stress to the individual that:

- everyone involved in their non-medical and medical exposure or treatment has been appropriately trained
- the examination or treatment is being undertaken because it is most likely to answer the clinical question and provide the most effective outcome
- the radiation dose will be personalised to them and, in the case of radiotherapy treatment, the dose will be specifically targeted

- risks associated with the proposed imaging examination will be minimised and controlled, and benefits maximised, using appropriate and relevant dose reduction techniques
- risks associated with radiotherapy dose will be evaluated and planned in such a way to maximise the dose delivered to the tumour whilst avoiding organs at risk

If, following conversation with the patient, a radiographer or AP has reason to believe the examination or treatment is no longer required or is inappropriate, it is their professional duty to seek further advice and clarification from the IR(ME)R Referrer and Practitioner. Any changes to the intended examination or treatment may need to be re-justified by the Practitioner, or re-authorised under guidelines issued by the Practitioner.

Dialogue between the IR(ME)R Operator (radiographer or AP) and the patient could include:

- An explanation of the benefit from the proposed examination or treatment. The ultimate purpose being that such benefit will outweigh any risk (IR(ME)R Regulation 11(1)(b)) and that this decision has been made by a trained individual.
 - » For example: A specialist in radiology/oncology believes you are more likely to benefit from this test/treatment than not
- The fact that the proposed examination is the best one to answer the clinical question.
 - » For example: This is the test considered most likely to answer the question your doctor is asking
- The risks to the patient of not having the examination or treatment (i.e. ongoing management of the patient may be hindered).
 - » For example: If we do not perform this test/proceed with this treatment the likely result is that you will become more unwell/we may not be able to give you the most effective treatment
- The fact that optimisation of the exposure to manage radiation dose, without loss of good quality diagnostic information, will always take place.
 - » For example: We will always provide the best possible images at the lowest dose practicable
- The fact that optimisation also takes place in radiotherapy.
 - » For example: We will target the area that needs to be treated and do everything possible to avoid healthy tissue

- The typical dose estimate¹² from the proposed examination (know your effective doses!). For further information see <u>Appendix 1</u> of this document and refer to *Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources*¹⁸. Consider the use of pictorial examples such as risk pie charts or dots charts⁷.
- A brief description of both the known risks (the deterministic tissue reactions) and the potential risks (the latent stochastic effects) from the proposed radiation exposure. It may be helpful to standardise how this information is delivered in an Employer's procedure.

Regarding the information contained in Appendix 1 of this document, some caution should be exercised when comparing effective doses from typical examinations to those received by the public as background radiation. The fact is that the dose delivered during a chest x-ray is so low that using it as a denominator to calculate the equivalent number of chest x-rays comparable with the level of dose of any other radiological procedure may be construed as misleading. The concept of natural background radiation will not necessarily be familiar to an individual, so the comparison between the dose associated with a radiological medical procedure and the equivalent period of exposure to natural radiation may not be readily understandable. An additional, potentially misleading feature when comparing individual radiation doses with equivalent natural background exposures is that background radiation involves whole body exposure, whereas diagnostic radiation doses, more often, have regional (more localised) exposures. Background radiation will also differ depending on geographical location¹⁹. The risk of developing cancer from low-level radiation exposure, such as that with diagnostic clinical imaging examinations, is not known with certainty at the individual patient level. In the absence of this certainty, a precautionary approach should be taken to assure that the radiation dose used to perform the examination does not exceed the dose necessary to produce an image of adequate diagnostic quality. To put this simply, the examination should always be about managing the radiation dose to be commensurate with the medical purpose (the clinical question). DRLs (diagnostic and therapeutic) used effectively in clinical practice are useful tools for governance and quality assurance.

Benefit and risk are not determined solely by radiation exposure parameters, but are influenced by Referrer, Practitioner and Operator knowledge, experience and practical skills, organisational culture, and processes such as local governance frameworks.

The SoR and CoR believe that self-reflection following dialogue with patients and service users is important to ensure ongoing practice improvement. Discussion with colleagues is also useful to build greater confidence in communicating risks.

It is recognised that radiographers and APs possess the skills to effectively communicate benefit and radiation risk information, but it is also believed that all healthcare professionals should, as part of

their continuing professional development, revise the principles of radiobiology, ionising radiation physics, and units of radiation dose measurement. These theoretical concepts were, and still are, included in the education programmes that lead to qualification, and form a compulsory part to prove "adequate training" as stipulated in IR(ME)R Schedule 3. Chapters one and two of the World Health Organization document *Communicating radiation risks in paediatric imaging: Information to support healthcare discussions about benefit and risk*⁸ serve as a very useful revision aid. In particular, some revision may be useful on the two principles of radiation protection:

- 1. Justification (i.e. doing the right examination at the right time)
- 2. Optimisation (i.e. ensuring the radiation dose is kept as low as reasonably practicable consistent with intended purpose)

2.4 Carers and comforters

IR(ME)R now applies to the exposure of ionising radiation to carers and comforters. It defines carers and comforters as "individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure"^{1–3}. There is no single way to consider and deliver information relating to benefit and risk for the comforter and carer. This should be done in the context of the need for the comforter and carer to be present, and is likely to be influenced by their relationship with the patient or service user. There should be locally agreed guidance and a written procedure that details the process for justification (or authorisation under guidelines issued by the IR(ME)R Practitioner) of exposures to comforters and carers, including who is entitled to do so. The SoR and CoR consider the use of carers and comforters appropriate for diagnostic procedures and diagnostic and therapeutic nuclear medicine procedures. Appropriate dose constraints should be established. It is not appropriate to use carers and comforters for radiotherapy exposures.

2.5 Typical patient scenarios

It is important to note that these scenarios may relate to conversations occurring **after** the examination has been appropriately justified. If the Operator discovers new information or clinical details coming to light as a result of a conversation with the individual receiving the exposure, the Operator is duty bound to discuss this with the Referrer or Practitioner. Authorisation is separate to justification and is the documented evidence that the exposure has been justified prior to the procedure²⁰. The SoR and CoR recognise that there may be situations where the Operator is not able to provide adequate information prior to the exposure because they are not involved with the patient

pathway at this time, for example when a patient is undergoing elective surgery. Where there is adequate opportunity to provide this information prior to exposure, the Employer's procedures should state who has the responsibility to do so.

Diagnostic scenario 1

A child has been referred for a chest x-ray, which has been justified by the IR(ME)R Practitioner. The child's mother asks whether it is safe and seeks assurance that her child will not develop cancer as a result.

Suggested dialogue:

The doctor looking after your child believes a chest x-ray will help to decide on the best treatment. A specialist in radiology agrees that this is the best test to answer the question your doctor has asked and that the benefit to your child of having the x-ray is greater than the risk. A chest x-ray involves a very low dose of radiation, about the same amount of radiation that you would normally get in 2 to 3 days from the radiation that is naturally occurring all around us. This exposure to ionising radiation represents a very low risk to your child of developing a cancer in the future. The dose delivered will be kept as low as is practicable.

Diagnostic scenario 2

Mr Smith is an 80 year old male with dementia who attends with his carer for an urgent CT scan of the head following a fall. His carer mentions that Mr Smith's family are concerned about the radiation risk as they have heard that CT is a high-dose test. The examination has been justified and the mental capacity legislation (appropriate to that country) has been followed with regards to assessing capacity to consent to treatment.

Suggested dialogue:

The doctor looking after Mr Smith believes a CT scan is the best way to quickly decide whether Mr Smith needs urgent treatment.

A specialist in radiology agrees that the benefits of Mr Smith having the CT scan are greater than the risks from the radiation dose or from not finding out what might be wrong. The scan involves a low dose of radiation, about the same as the amount of radiation exposure you would normally get in a year from naturally occurring background radiation.

Note: Information may not always be given directly to the patient or service user but that does not mean it is not practicable to do so.

Diagnostic scenario 3

A patient who is intubated or unconscious.

IR(ME)R Schedule 2 (i) states that wherever practicable the provision of information relating to the benefits and risks associated with the radiation dose from the exposure occurs prior to the examination taking place. If it is not practicable (or safe), for example in the case of a patient who is unable to communicate, and where there is clear benefit and urgency identified in the justification process, the operator may proceed to carry out the exposure without providing prior information to the patient or those that care for them.

The SoR and CoR recommend that there is documented evidence for this decision recorded in the patient's notes or on the Radiology Information System (RIS).

For example:

This examination was justified by (the Practitioner) as urgent and the patient was unconscious/ intubated. Priority was given to completion of the examination over providing prior information relating to benefit and risk.

Diagnostic scenario 4

A patient who has had multiple examinations involving exposures of ionising radiation asks how many examinations they can safely have.

Suggested dialogue:

Each exposure must be justified which means an expert radiology practitioner believes there is sufficient net benefit to you of having this examination when weighed against the risks. Whilst the cumulative effect of your lifetime exposure to ionising radiation is taken into consideration, each new exposure is justified on its own merits and in light of the current question. The benefit to you is weighed against the risk of not having the examination and the availability of alternative techniques that do not involve ionising radiation. Each exposure is made using as low a dose of radiation as is reasonably practicable consistent with your individual needs.

2.6 Communicating benefit and risk in radiotherapy

A discussion on benefit versus risk in a therapeutic radiography setting should initially be undertaken as part of the informed consent process. It is a fundamental requirement that the therapeutic radiographer ensures a patient has given informed consent before proceeding with any clinical procedure. Therapeutic radiographers working as IR(ME)R Operators should have the knowledge and skills to discuss the benefits and risks of a therapeutic radiation exposure.

Traditionally, informed consent for radiotherapy would be carried out by a clinical oncologist or their registrar. Now, it is common for informed consent to be carried out by appropriately trained and entitled radiographers working in advanced and consultant practitioner roles. These radiographers should be familiar with the requirement to discuss benefit versus risk of the radiation exposure required for the planning and delivery of a patient's radiotherapy treatment. This should include the reason why the treatment is considered the best option for the patient and how it is specifically planned for each individual. It should also be made clear that every patient responds differently to radiotherapy treatment.

The likelihood of acute and late side effects occurring during the patient's treatment should be balanced with the risks associated with receiving no treatment. This should be a dynamic dialogue between the therapeutic radiographer and the patient. The patient should be encouraged and supported to voice their concerns and ask questions. The therapeutic radiographer should always ensure that the patient understands the benefits and risks of their treatment pathway.

Therapeutic scenario 1

A patient has been referred for radiotherapy to treat prostate cancer. He is scheduled to receive 32 fractions. His friend recently underwent radiotherapy for prostate cancer and received 20 fractions. He is concerned of the risks of receiving "more treatment".

Suggested dialogue:

Your doctor has decided on the appropriate number of treatments and a dose for your individual case. The radiotherapy dose is very carefully planned to be delivered accurately to the appropriate area and the benefits of this treatment far outweigh any risks of damage to healthy tissue.

Therapeutic scenario 2

A patient is receiving radiotherapy as planned by a clinical oncologist. During treatment, the patient's set-up varies from day to day and the radiographers acting as IR(ME)R Practitioners decide to conduct additional verification images to ensure accuracy. The patient queries why they are receiving extra doses for these images each day.

Suggested dialogue:

Your doctor has requested that we deliver radiotherapy in this way to treat your cancer. To do this accurately we must ensure that your position is consistent each day to maximise radiation dose to the diseased tissue and minimise radiation dose to your healthy tissue. The dose produced by the verification x-rays is very low and we consider the benefits of delivering your radiotherapy accurately outweigh the risks of these daily verification images.

Therapeutic scenario 3

A patient has been referred for a planning CT scan with a breath hold to plan deep inspiration breath hold (DIBH) radiotherapy treatment for cancer of her left breast. The patient managed to hold her breath to appropriate thresholds during practices but during the scan she struggled to hold her breath for long enough and breathed out mid-scan. The radiographers noted that the patient had been exhausted during the practices and deemed that she would not manage breath hold treatment. They decide, as per the local Employer's procedures, to conduct a further freebreathing CT planning scan so that standard radiotherapy can be planned.

The patient was told by her oncologist that breath hold techniques allow the heart to be removed from the treatment field. Having been given this information, she is concerned that her heart will be damaged during free-breathing radiotherapy and wishes to attempt a breath hold scan again.

Suggested dialogue:

If we performed another scan with you holding your breath and you were unable to manage this again, you would have received two CT scans that cannot be used to plan your radiotherapy. We believe it is safest to perform a scan with you breathing normally which can be used to plan your radiotherapy.

Your doctor has requested that a planning scan be conducted to plan radiotherapy for your left breast cancer. Breath hold scanning and treatment are in accordance with the standard treatment protocol for this type of radiotherapy; however, it is very common for patients to not be able to hold their breath for the appropriate time. In this case we conduct a planning scan with you breathing normally. When your doctor looks at your images they will be able to see if your heart will be affected by the radiation. If this is the case, they will use planning techniques to minimise the dose to your heart, to achieve similar levels as if you were treated holding your breath.

Note: The discussion of benefit and risk should always be performed before the exposure.

3 Summary

Providing an individual, wherever practicable, with adequate information relating to the benefits and risks associated with a radiation dose before exposure takes place, became a regulatory requirement under IR(ME)R^{1–3} on 6 February 2018. The UK radiology and radiotherapy workforce must ensure local policies and procedures assure compliance with the regulations, to meet public expectation and improve the experience of individuals undergoing medical and non-medical exposures of ionising radiation. IR(ME)R duty holders should be adequately trained and entitled to provide individuals with appropriate and timely information, enabling them to understand their personal risks within the context of their benefits.

The use of supplementary materials such as patient information leaflets and posters may help to accommodate a range of communication preferences. Communication processes should primarily highlight the benefit of exposure and be proportional to the risk of the dose of ionising radiation, as well as the risk of delaying, not having, or completing the procedure/treatment. Conversations should be tailored to the individual. Scenarios suggested within this guidance document and within the World Health Organization guidance⁸ serve to illustrate and support clinical practice and are intended to be used as the building blocks of such conversations.

Communicating benefit and risk information to patients is not only a statutory requirement, but the SoR and CoR consider it to be a core component of professional practice. It provides an opportunity for individuals to express what matters to them, which is central to the SoR and CoR strategies^{14,15}. Meeting the requirements of the Quality Standard for Imaging⁶ ensures consistency in the care provided can be assured. Finally, communicating with patients and service users about the benefits and risks of ionising radiation is integral to compassionate and values-based care.

Appendix 1

In the United Kingdom, UKHSA has calculated that, on average, people are exposed to about 2.7 millisieverts (mSv) of radiation per year from naturally occurring radiation in homes and workplaces¹⁰.

The following data demonstrate typical dose estimates from a range of diagnostic clinical imaging examinations — adapted from the UKHSA Ionising radiation: dose comparisons¹².

Comparison of doses from sources of exposure

Source of exposure	Dose
Dental x-ray	0.005 mSv
100g of Brazil nuts	0.01 mSv
Chest x-ray	0.014 mSv
Transatlantic flight	0.08 mSv
Nuclear power station worker average annual occupational exposure (2010)	0.18 mSv
UK annual average radon dose	1.3 mSv
CT scan of the head	1.4 mSv
UK average annual radiation dose	2.7 mSv
USA average annual radiation dose	6.2 mSv
CT scan of the chest	6.6 mSv
Average annual radon dose to people in Cornwall	6.9 mSv
CT scan of the whole spine	10 mSv
Annual exposure limit for nuclear industry employees	20 mSv
Level at which changes in blood cells can be readily observed	100 mSv
Acute radiation effects including nausea and a reduction in white blood cell count	1000 mSv
Dose of radiation which would kill about half of those receiving it in a month	5000 mSv

References

1. The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024. Available from: <u>https://www.legislation.gov.uk/uksi/2024/896/contents/made</u> [accessed February 5, 2025].

2. The Ionising Radiation (Medical Exposure) Regulations 2017. Available from: <u>https://www.</u> <u>legislation.gov.uk/uksi/2017/1322/contents/made</u> [accessed June 30, 2023].

3. The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018. Available from: <u>https://www.legislation.gov.uk/nisr/2018/17/contents/made</u> [accessed June 30, 2023].

4. Council Directive 2013/59/Euratom. Available from: <u>https://eur-lex.europa.eu/eli/dir/2013/59/</u> <u>oj/eng</u> [accessed March 10, 2025].

5. The Standards of proficiency for Radiographers (2023). The HCPC. Available from: <u>https://www.</u> <u>hcpc-uk.org/standards/standards-of-proficiency/</u> [accessed March 14, 2025].

6. Quality Standard for Imaging. CoR. Available from: <u>https://www.collegeofradiographers.ac.uk/</u> <u>about-the-college/qsi</u> [accessed March 20, 2025].

7. Kasraie N., Jordan D., Keup C., Westra S. Optimizing Communication With Parents on Benefits and Radiation Risks in Pediatric Imaging. J Am Coll Radiol 2018;15(5):809–17. Doi: 10.1016/j. jacr.2018.01.032.

8. Communicating radiation risks in paediatric imaging: Information to support healthcare discussions about benefit and risk. Available from: <u>https://www.who.int/publications/i/item/978924151034</u> [accessed March 20, 2025].

9. National Diagnostic Reference Levels (NDRLs) from 20 November 2024. GOV.UK. Available from: <u>https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/ndrl</u> [accessed March 20, 2025].

10. Siegrist M., Cvetkovich G. Perception of Hazards: The Role of Social Trust and Knowledge. Risk Anal 2000;20(5):713–20. Doi: 10.1111/0272-4332.205064.

11. Portelli JL., McNulty JP., Bezzina P., Rainford L. Benefit-risk communication in paediatric imaging: What do referring physicians, radiographers and radiologists think, say and do? Radiography 2018;24(1):33–40. Doi: 10.1016/j.radi.2017.08.009.

12. Ionising radiation: dose comparisons. GOV.UK. Available from: <u>https://www.gov.uk/government/</u> <u>publications/ionising-radiation-dose-comparisons/ionising-radiation-dose-comparisons</u> [accessed March 20, 2025].

13. Five Year Forward View (2014). Available from: <u>https://www.england.nhs.uk/wp-content/</u><u>uploads/2014/10/5yfv-web.pdf</u>.

14. Society of Radiographers Strategy 2021 - 2024. SoR. Available from: <u>https://www.sor.org/</u> <u>about/society-of-radiographers/statutory-documents/society-of-radiographers-strategy-2021-2024</u> [accessed March 20, 2025].

15. College of Radiographers Strategy 2021 - 2024. CoR. Available from: <u>https://www.</u> <u>collegeofradiographers.ac.uk/about-the-college/statutory-documents/college-of-radiographers-</u> <u>strategy-2021-2024</u> [accessed August 3, 2023].

16. Patient Public and Practitioner Partnerships within Imaging and Radiotherapy: Guiding Principles. SoR. Available from: <u>https://www.sor.org/learning-advice/professional-body-guidance-and-publications/documents-and-publications/policy-guidance-document-library/patient-public-and-practitioner-partnerships-withi [accessed February 12, 2025].</u>

17. Values-based Practice in Diagnostic & Therapeutic Radiography: A Training Template. SoR. Available from: <u>https://www.sor.org/learning-advice/professional-body-guidance-and-publications/</u> <u>documents-and-publications/policy-guidance-document-library/values-based-practice-in-diagnostic-</u> <u>therapeutic-ra</u> [accessed March 20, 2025].

18. Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources. Available from: <u>https://assets.publishing.service.gov.uk/</u> <u>media/67b4b2ba4a80c6718b55bf42/Notes-for-guidance-on-the-clinical-administration-of-</u> <u>radiopharmaceuticals-and-use-of-sealed-radioactive-sources-18-02-2025.pdf</u>.

19. Radiology (ACR) RS of NA (RSNA) and AC of. Radiation Dose. Radiologyinfo.Org. Available from: <u>https://www.radiologyinfo.org/en/info/safety-xray</u> [accessed March 20, 2025].

20. Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017. GOV.UK. Available from: https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017- guidance-to-the-ionising-radiation-medical-exposure-regulations-2017- https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017- guidance-to-the-ionising-radiation-medical-exposure-regulations-2017 [accessed March 21, 2025].

