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Social Care

# Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017

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# 1. Introduction

This document provides guidance to accompany [the Ionising Radiation \(Medical Exposure\) Regulations 2017](#), ("the Regulations") and should therefore be read in conjunction with the Regulations. This Guidance document is not intended to be binding and cannot take the place of legal advice. It is a guide to help explain how certain provisions of the Regulations should be interpreted and may be used as a point of reference by the enforcement authorities when reaching decisions about enforcement. However, the ultimate arbiter in any case of doubt would be the Court: only it could make a definitive ruling on the interpretation of the legislation.

This Guidance is also applicable to the [Ionising Radiation \(Medical Exposure\) Regulations \(Northern Ireland\) 2018](#) and any reference to "the Regulations" can be taken to refer to these also, unless otherwise stated. Any specific differences concerning the Regulations for Northern Ireland are noted in the text.

The Regulations implement for Great Britain (and Northern Ireland) in part, provisions of Council Directive 2013/59/Euratom of 5 December 2013 (the "Basic Safety Standards Directive") laying down the basic safety standards for protection against the dangers from exposure to ionising radiation. The Regulations address the radiation protection of persons undergoing medical exposures whether as part of their own medical diagnosis or treatment, as part of research, as asymptomatic individuals, as those undergoing non-medical imaging using medical radiological equipment or as carers and comforters of persons undergoing medical exposures.

The Regulations impose duties on employers and those with responsibilities for undertaking activities covered by the legislation, including optimising and justifying medical exposures and administering ionising radiation. While overall the Regulations broadly reflect existing provisions, they also introduce additional requirements which act to enhance protection for those undergoing medical exposures:

- the Regulations expand requirements for reporting of accidental or unintended exposures to ionising radiation to include doses that are less than intended
- the Regulations formalise the recognition of medical physics experts (MPEs)
- the Regulations introduce requirements for licensing of the administration of radioactive substances to persons for diagnosis, treatment or research.

The Regulations revoke and replace:

- the Ionising Radiation (Medical Exposure) Regulations 2000 (in Northern Ireland the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000)
- the Medicines (Administration of Radioactive Substances) Regulations 1978
- the Medicines (Radioactive Substances) Order 1978.

They provide consequential amendment of:

- the Justification of Practices Involving Ionising Radiation Regulations 2004
- the Human Medicines Regulations 2012
- the Ionising Radiations Regulations 2017.

The Basic Safety Standards Directive requires that all exposures to ionising radiation must be justified prior to the exposure being made. The Directive refers to two levels of justification: justification of types of practice for all categories of exposure; and justification of individual

exposures for medical and non-medical imaging purposes, where medical radiological equipment is used.

The Regulations apply only to individual exposures. Justification of types of practice involving medical and non-medical imaging exposures is covered by the Justification of Practices Involving Ionising Radiation Regulations 2004.

Practice involving the use of ionising radiation in the NHS and the private sector of healthcare is broadly consistent and the Guidance applies to both the NHS and the private sector.

## 2. Interpretation – Regulation 2

This regulation defines a number of terms used in the Regulations. Certain key definitions are discussed below:

### **“carers and comforters”**

Carers and comforters are individuals who are knowingly and willingly exposed to ionising radiation through support and comfort of those undergoing exposure. The definition makes clear that individuals undertaking this role are not those doing so as part of their employment. Carers and comforters are commonly relatives or friends of those undergoing exposure.

### **"employer"**

The definition of the employer under these Regulations is someone other than an employee who, in the course of a trade or business carries out or engages others to carry out, medical exposures or practical aspects.

The legal duties of the employer under these Regulations cannot be delegated to another and the employer should be identified so that duties placed on the employer can be attributed and fulfilled for the relevant activities laid out in Regulations. In circumstances where more than one employer may exist for certain aspects of an exposure, cooperation between employers is recommended to agree the roles and responsibilities of each party. In practice, the designated employer for each aspect of the exposure would usually be the person best placed to undertake the functions and responsibilities required in the Regulations.

### **"Licensing Authority"**

The Licensing Authority for the Regulations applies only to the administration of radioactive substances.

For practitioners in Great Britain, the Licensing Authority will be the Secretary of State, in Northern Ireland this will be the Department of Health for Northern Ireland. Only one licence is required regardless of where the practitioner is entitled as a duty holder.

For employers, there will be different Licensing Authorities for England, Scotland, Wales and Northern Ireland. Employer licences are specific to each medical radiological installation.

### **“medical physics expert”**

The Regulations require medical physics experts (MPEs) to be appropriately educated and trained, and to be recognised by the Secretary of State. Further details on the MPE recognition scheme can be found on the [GOV.UK website](https://www.gov.uk).

The functions of the MPE role are different to that of the radiation protection adviser or radioactive waste adviser, as defined under other radiation protection regulations, although, in practice, it is possible that the same person may undertake more than one role.

### **"non-medical imaging exposure"**

Non-medical imaging exposures within these Regulations are those deliberately undertaken using medical radiological equipment which do not confer a health benefit to the individual exposed. They are carried out for purposes other than those described in regulation 3 (a) – (e). Examples of non-medical imaging using medical radiological equipment include, but are not limited to:

- (i) health assessment for employment purposes
- (ii) health assessment for immigration purposes

- (iii) health assessment for insurance purposes
- (iv) radiological age assessment
- (v) identification of concealed objects within the body.

**“operator”**

An operator is anyone who is entitled by the employer to carry out a practical aspect (see "practical aspect" below).

An operator usually will carry out a range of functions as part of their employment and Schedule 2(1)(b) requires entitlement and the scope of practice of operators to be clearly defined within the employer's written procedures.

**"practical aspect"**

Practical aspects are defined as the physical conduct of medical exposures. The range of functions covered by this term is extensive and includes the supporting functions prior to the exposure taking place, such as routine performance testing of equipment as required by regulation 15(3), the preparation of radiopharmaceuticals, treatment planning and calculation of monitor units to be delivered in radiotherapy, as well as performing the exposure itself. The term also includes activities undertaken after the exposure has taken place, image processing and archiving.

**"practitioner"**

A practitioner must be a registered health care professional, as defined by the Regulations. Practitioners are entitled by the employer to take responsibility for an individual exposure. Schedule 2(1)(b) requires entitlement and the scope of practice of practitioners to be clearly defined within the employer's written procedures.

For exposures involving administration of radioactive substances, the practitioner must be licensed in accordance with regulation 5 and all practitioners need to be adequately trained to undertake this function, as outlined in regulation 17(1).

**“radioactive substance”**

Radioactive substances are substances containing one or more radionuclides that cannot be disregarded from a radiation protection point of view. Due to variations in the way different radioactive substances are metabolised and concentrated in the body, an absolute level of radioactivity is not more closely defined. In practice, substances containing only naturally occurring radionuclides in normal concentrations, e.g. naturally occurring potassium, would not normally be included in this definition for the purposes of licensing.

**“referrer”**

A referrer must be a registered health care professional. Referrers are responsible for referring individuals to the practitioner for specific exposures to be undertaken in accordance with the employer's recommendations for referral criteria in regulation 6(5)(a). Schedule 2(1)(b) requires entitlement and the scope of practice to be clearly defined within the employer's written procedures.

For Northern Ireland, the definition of referrer has been broadened slightly to allow for situations where medical practitioners in the Republic of Ireland (registered with the Medical Council of Ireland) could be entitled in line with employers procedures and agreements between healthcare bodies to refer individuals for exposures in Northern Ireland.

**“relevant enforcing authority”**

The enforcing authority for the Regulations is appropriate to each of the countries to which the Regulations apply. As stated in the Regulations, for England the Care Quality Commission is the enforcing authority. For Scotland this is Healthcare Improvement Scotland and for Wales this is Healthcare Inspectorate Wales, as specified by the relevant Ministers. In Northern Ireland the Regulation and Quality Improvement Authority has been specified by the Department of Health to provide enforcement and inspection activities.

### **"unintended exposure"**

An unintended exposure is one that was not intended per se or which is significantly different from that intended by the practitioner (taking into account appropriate variation in accordance with the need to optimise exposures). Such exposures might include but are not limited to circumstances where an individual receives the wrong exposure (including circumstances where the referral was made for the wrong individual), an exposure involving inappropriate exposure factors or administered activity, where the wrong part of the body is exposed, or where the exposure is not delivered within accepted tolerances.

### **Regulation 2(2)**

In some cases, a single individual may act as more than one duty holder (for example, some dental practitioners). Such individuals should be clear on their responsibilities as each of these duty holders under the Regulations and comply with all regulatory requirements. Where an employer carries out other duty holder tasks, the employer is still required to establish the procedures required by this regulation and to comply with them.

### 3. Application – Regulation 3

This regulation lists the range of exposures to ionising radiation to which the Regulations apply, introducing exposures to carers and comforters, asymptomatic individuals and individuals undergoing non-medical imaging using medical radiological equipment.

## 4. The Licensing Authority – Regulation 4

This regulation establishes the basis by which the Licensing Authority may issue a licence to those required to hold one, as detailed in regulation 5. Licences may be issued for a set period of time and may be subject to conditions. The Licensing Authority may vary or revoke licenses at any time. Some licences may require a fee to be paid before they can be issued and further information on fees is provided in Schedule 1.

Operational aspects of licensing will be carried out by Public Health England (PHE) on behalf of the Licensing Authorities, advised where appropriate by the Administration of Radioactive Substances Advisory Committee (ARSAC).

## 5. Requirement to hold a licence – Regulation 5

This regulation establishes the requirement for certain persons to hold a valid licence:

1. A separate licence is required by the Employer, at each installation where the administration of radioactive substances will take place for a specified purpose.
2. A licence is required by a practitioner in order to administer radioactive substances for a specified purpose.

Purpose is defined as being either for diagnosis, treatment or research and will be specified on the licence.

This regulation replaces previous requirements for practitioners to hold a certificate under the Medicines (Administration of Radioactive Substances) Regulations 1978 and the Medicines (Radioactive Substances) Order 1978.

Further information relating to applications for licences and the review processes is given in Schedule 1.

## 6. Employer's duties: establishment of general procedures, protocols and quality assurance programmes – Regulation 6

### **Regulation 6(1)**

This regulation requires the employer to establish written procedures. These are intended to provide a framework under which professionals can practice. It is recommended that the employer seek advice from professional colleagues from relevant specialties in establishing the procedures.

Procedures listed in Schedule 2 of the Regulations are not exhaustive. It is recommended that written procedures should be considered controlled documents: reviewed at regular intervals according to the procedure in Schedule 2(1)(d) and as required in regulation 6(5)(b); approved according to agreed practice; and archived appropriately.

### **Regulation 6(3)**

This regulation requires the employer to ensure that practitioners and operators are both adequately trained and undertake continuing education and training.

However, it is to be noted that the duty is not on the employer to provide continuing education and training but to take steps to ensure that the practitioner and operator undertake education and training. In accordance with regulation 2(2), where the employer is also the practitioner or operator (or both), the employer must ensure that appropriate continuing education and training is undertaken.

In cases where the employer engages and entitles individuals as practitioners and operators, other than those who are employees, it is recommended that it is agreed, for example in the contract, that the practitioner or operator to be engaged must have been adequately trained and undertakes continuing education and training.

It is recommended that, where practicable, all practitioners and operators engaged to carry out exposures are trained locally on the equipment they use.

### **Regulation 6(4)**

It is the responsibility of the employer to ensure, where appropriate, that written protocols are in place for every type of standard radiological practice covered by the Regulations. The protocols required under this regulation should not be confused with employer's written procedures required by regulation 6(1).

Protocols might include, for example, the exposure factors used, dose to be delivered or specific techniques used to deliver ionising radiation. It is recommended that protocols are developed by appropriate, experienced professionals and that consideration is given to healthcare pathways. A multi-disciplinary team approach may be appropriate.

In practice, it may not always be possible to produce detailed and rigid protocols for every medical and non-medical imaging exposure, but it is recommended that where possible, protocols should be evidence based, specific to each examination and machine, and that any deviations are recorded. For example, in radiotherapy, written protocols might refer to standard dose regimes, energies and beam projection. Such protocols do not negate the need for individual planning to produce the intended therapeutic effect.

Protocols must be written down and it is recommended that they are maintained, accessible and their status as controlled documents understood. Regulation 6(5)(b) requires the employer to establish quality assurance programmes for written protocols.

#### **Regulation 6(5)(a)**

The employer must ensure the referral guidelines for medical exposures required under this regulation are available to all entitled referrers to that department. There is an obligation to have these guidelines in place regardless of the size or type of the department or types of examinations performed.

In establishing the referral guidelines, it is recommended to consult and agree these with professionals involved in medical exposures. Many departments may already have guidelines in place and information supplied by professional medical bodies may be useful, for example the Royal College of Radiologists has produced recommendations for diagnostic practice which include dose information.

Referral guidelines are required for concomitant exposures in radiotherapy that are included as an adjunct to treatment, where these are not included within the radiotherapy protocol or where separate justification is required. It is recommended that referral guidelines for therapy and planning exposures include requirements for confirming disease by specific criteria such as imaging or histopathology.

#### **Regulation 6(5)(b)**

This regulation requires the employer to establish quality assurance programmes for written procedures and protocols. Quality assurance programmes for equipment are dealt with under regulation 15.

In practice, each of the employer's written procedures and protocols in a quality assurance programme of this type could be in the form of a controlled document which may include:

- who is responsible for authorising the document, on behalf of the employer
- who is responsible to the authorising person for the accuracy of the document content, for document review, and for ensuring the document is up to date
- a formal process for making changes
- the version number
- the date of the last and next scheduled review
- page numbering.

#### **Regulation 6(5)(c)**

This regulation requires the employer to regularly review and make available local diagnostic reference levels for exposures identified in regulations 3(a), (b), (e) and (f). It is important to note the definition of diagnostic reference levels refers to typical examinations for standard sized patients or phantoms for broadly defined types of equipment. Examples of national diagnostic reference levels include those produced by ARSAC and PHE.

National or European diagnostic reference levels must be taken into account where available for standard diagnostic exposures, and where appropriate, diagnostic reference levels for interventional radiology examinations should be provided; acknowledging, for example, that there may be limited data for certain exposures. Diagnostic reference levels for non-medical imaging must be established where practicable, for example this may include such exposures which are undertaken on a routine basis.

For exposures where diagnostic reference levels are not available, the exposures must still be optimised, as under regulation 12, taking into account the exposure used for similar procedures if appropriate. Adherence to diagnostic reference levels below national or European values alone may not necessarily be sufficient to meet all requirements for optimisation.

#### **Regulation 6(5)(d)(i)**

This regulation requires dose constraints to be established by the employer for research protocols involving standard radiodiagnostic procedures, where no health benefit is expected for the individual exposed. Such research should be subject to a dose constraint based on the total dose from all radiodiagnostic procedures included in the protocol.

#### **Regulation 6(5)(d)(ii)**

This regulation requires dose constraints to be established for carers and comforters, which should be set locally. It is suggested that a dose constraint of 5mSv can be considered appropriate for most circumstances. However, it is accepted that there will be a wide variety of circumstances involving exposure to carers and comforters which may arise, and this regulation allows the employer flexibility in setting dose constraints for carers and comforters locally. It is recommended that on occasions when a higher value may be appropriate, such as where the carer or comforter is supporting the treatment of a vulnerable individual, dose constraints should be assessed and agreed on a case-by-case basis, making clear to the carer and comforter the risks involved.

#### **Regulation 6(7)**

Under this regulation the employer is required to ensure reviews are undertaken at a local level, to evaluate the reasons why diagnostic reference levels have been consistently exceeded. To comply with this regulation, corrective action might include setting new values for local diagnostic reference levels (see regulation 6(5)(c) and accompanying notes) or retraining an individual.

This regulation is not intended to replace or diminish the need for regular reviews of diagnostic reference levels.

#### **Regulation 6(8)**

This regulation requires the employer to take steps to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding. It is advised that this should not be restricted to enquiries by operators prior to exposure and might include measures such as signs in waiting rooms or inclusion of relevant information in appointment letters, where appropriate.

## 7. Employer's duties: clinical audit – Regulation 7

This regulation requires the employer's procedures to provide for the carrying out of clinical audit as appropriate. In doing so, the employer may wish to take account of existing professional guidance specific to the subject.

Clinical audit activities relating to healthcare involving exposures to ionising radiation may be carried out by a range of professionals, but in all cases consideration should be given to radiation protection aspects. For example, audit of a healthcare pathway might include consideration of the role of imaging within the pathway and its benefits in relation to overall outcome. Clinical audit can result in better optimisation of exposures, both individually and collectively as part of a pathway as a whole and it is recommended that results of clinical audit should be made available to the employer.

## 8. Employer's duties: accidental or unintended exposure – Regulation 8

This regulation provides a comprehensive system for analysis, recording and reporting of accidental or unintended exposures. It includes events which are the consequence of equipment or procedural failure. The term “accidental or unintended exposure” does not in itself define when an event is considered significant and should be notified to the appropriate enforcing authority. This is considered under regulation 8(4).

The requirements are consistent with duty of candour.

Documentation relating to potential and actual incidents should be retained in line with relevant guidance, including that published by the enforcing authorities.

### **Regulation 8(1)**

It is important that where accidental or unintended exposures are clinically significant, the appropriate professionals involved with the care of a patient are aware that such an incident has taken place and that details are shared with them, to provide for the patient being informed and to ensure that appropriate care can be provided for the patient in the future. Clinically significant exposures are not defined by the relevant enforcing authorities. It is intended that guidance on these will be issued jointly by appropriate clinical and medical professional bodies in collaboration with the Health Departments.

The regulation allows for circumstances where it is not in the best interests of the patient to be informed of such an exposure. For example, delivery of radiotherapy to a patient undergoing palliative treatment, where the effects of an unintended or accidental exposure are unlikely to become apparent in the remaining life of the individual, but being informed of the incident may have a detrimental effect on the patient's well-being. Such circumstances will be exceptional and in practice the practitioner and the referrer should be involved in this decision and the basis for the decision recorded in the patient's notes. In such cases however, it is recommended that a representative of the patient is informed wherever possible.

The requirements of this regulation are consistent with the general need to conduct clinical practice in an open and transparent environment.

### **Regulation 8(2)**

This regulation recognises that radiotherapy exposures tend to have the potential for the greatest detriment in cases of accidental or unintended exposures (either to an individual or to a group of patients undergoing similar treatment) and requires employers to include a study of risk within associated quality assurance programmes. Quality assurance programmes relating to all exposures to which the Regulations apply are required generally, as addressed in regulation 6(5)(b) and 15.

### **Regulation 8(3)**

This regulation requires that systems for recording analyses of events are put in place, commensurate with the risk of the practice. Therefore, in practice, those relating to radiotherapy will tend to be more rigorous than those for general diagnostic radiography.

Such systems must address both near misses and errors. Applicable events are additional to those notifiable to the relevant enforcing authority in regulation 8(4)(b)(iv). In practice, this is a requirement of administrative processes already in place.

## **Regulation 8(4)**

This regulation requires the employer to carry out immediate preliminary investigations of accidental or unintended exposures.

This regulation applies to any exposure which has or may have involved significantly greater levels of ionising radiation than considered proportionate in the circumstances; as well as radiotherapeutic exposures which have or may have involved significantly lower levels of ionising radiation than considered proportionate in the circumstances. Unless the preliminary investigation shows beyond a reasonable doubt that such an exposure has not occurred, the relevant enforcing authority must be immediately notified and the employer must arrange for a detailed investigation of the exposure, which should include:

- establishing what happened
- identifying the causes and contributory factors of the failure
- remedial action to minimise the chance of a similar failure
- estimating the doses involved.

The employer must inform the relevant enforcing authority of the outcome of the detailed investigation and any corrective action taken, within the time frame specified by the relevant enforcing authority.

Notification is required to be made directly to the relevant enforcing authority appointed for these Regulations. Further guidance will be provided by the relevant enforcing authorities.

## 9. Relevant enforcing authority's duties: accidental or unintended exposure – Regulation 9

This regulation requires the relevant enforcing authorities to put in place mechanisms to provide information on significant events, to enable learning from experience and implementation of preventative measures, so that the probability of similar events is minimised. This may be provided through annual reports or specific case studies, as deemed appropriate by the relevant enforcing authority.

# 10. Duties of the practitioner, operator and referrer – Regulation 10

Regulation 10 sets out the respective responsibilities of practitioners, operators and referrers.

## **Regulation 10(1)**

The practitioner and the operator must comply with the employer's procedures, including those listed in Schedule 2.

## **Regulation 10(3)**

This regulation deals with the allocation of responsibility for practical aspects of an exposure to specific individuals entitled to act in this respect, in accordance with the employer's procedures (see Schedule 2(1)(b)). The person to whom a practical aspect has been allocated, the operator as defined in regulation 2, is responsible for that aspect (see regulation 10(4)).

## **Regulation 10(5)**

Regulation 10(5) specifies that the referrer plays a role in the justification process by providing relevant medical data to the practitioner, but the referrer does not undertake justification itself.

In order for the data to be sufficient for the purposes of justification, it may be necessary to include previous diagnostic information or medical records such as the clinical question being addressed, which is particularly relevant in the case of diagnostic exposures, or information relating to pregnancy and breastfeeding, where known. It may also be helpful to include information relating to clinical conditions which mean pregnancy and breastfeeding are not possible, to prevent inappropriate questioning of such individuals prior to an exposure taking place when this would normally be considered appropriate.

# 11. Justification of individual exposures – Regulation 11

This regulation deals with the justification and authorisation of individual exposures and provides that no one may carry out an exposure unless the matters set out in regulation 11(1)(a)-(f), where applicable, have been complied with. Points to draw attention to under this regulation are as follows:

## **Regulation 11(1)**

In this regulation, the phrase "carry out an exposure" refers to the actual process of exposure to ionising radiation itself, and not to other practical aspects of the exposure, such as calibration, which can be carried out irrespective of the justification of individual exposures.

## **Regulation 11(1)(a)**

For exposures involving the administration of radioactive substances, the justification and authorisation of exposures must only take place when both employer and practitioner licences have been issued. Regulation 20 provides guidance on transitional arrangements. These licences must include the specific radioactive substance to be administered and the purpose of the exposure.

## **Regulation 11(1)(b)**

This regulation requires that any exposure must be justified before the exposure can take place. The practitioner is responsible for the justification of each individual exposure. In practice, this should be based on evidence where available, for example, knowledge of the hazard associated with the exposure and the clinical information supplied by the referrer.

Regulation 11(1)(b) requires a practitioner to give appropriate weight to the matters set out in regulation 11(2) in determining whether an exposure shows a sufficient net benefit and can be justified. This means that the practitioner needs to consider and balance as appropriate the elements set out in regulation 11(2).

## **Regulation 11(1)(c)**

Authorisation is a process separate to justification and is the means by which it can be demonstrated that justification has been carried out. The method of authorisation may depend on local circumstances; in practice this may include an electronic signature or a signature on a request card. It is recommended that the employer specify a method of authorisation to be used locally to ensure a consistent approach.

The Regulations require that authorisation is carried out before the exposure takes place. In most circumstances, this does not present problems, particularly if opportunities provided by role extension and by regulation 11(5) are utilised.

## **Regulation 11(1)(d)**

The definition of an ethics committee is given in regulation 11(6).

Research involving the administration of radioactive substances must additionally be approved by the expert advisory committee ARSAC. ARSAC approval of a study does not replace the requirement for justification of exposures on an individual level.

### **Regulation 11(1)(e)**

These Regulations introduce justification of non-medical imaging exposures using medical radiological equipment. In such cases, the benefits may be financial or social rather than for the health of the individual being exposed.

### **Regulation 11(2)**

In the process of justification under regulation 11(1)(b) appropriate weight is to be given to the factors specified in regulation 11(2).

### **Regulation 11(3)(a)**

In justifying an exposure which is to an individual as part of a health screening programme, the practitioner must justify the exposure under regulation 11(1)(b) and appropriate weight must be given to the matters set out in regulation 11(2). In doing so, the practitioner is required by this regulation to have particular regard to recommendations from appropriate medical scientific societies or relevant bodies.

### **Regulation 11(3)(b)**

Where there is to be an exposure to a carer or comforter, the practitioner is required to justify the exposure under regulation 11(1)(b) and appropriate weight must be given to the matters set out in regulation 11(2). In doing so, the practitioner must have particular regard to the matters set out in regulation 11(3)(b).

Regulation 11(3)(b)(ii) refers to the possible benefits to the carer or comforter. These benefits are likely to be psychological rather than physical.

Individual justification of exposures to carers and comforters is required in addition to the justification required for the associated patient or non-medical imaging exposure. The appropriate matters in regulations 11(2) and 11(3) should have been considered separately with regard to the associated patient or the individual undergoing non-medical imaging exposure as part of the justification process for those individuals.

### **Regulation 11(3)(c)**

When justifying an exposure in the case of asymptomatic individuals, the practitioner must justify the exposure under regulation 11(1)(b) and appropriate weight must be given to the matters set out in regulation 11(2). In doing so, the practitioner is required by this regulation to take into account guidelines issued by appropriate medical scientific societies, relevant bodies or the Secretary of State. This applies to exposures of all asymptomatic individuals, including exposures for individual health assessment.

### **Regulation 11(3)(d)**

This regulation applies in cases where the practitioner is justifying an exposure to an individual where pregnancy cannot be excluded, particularly if abdominal or pelvic regions are involved; or in cases involving administration of radioactive substances to an individual who is breastfeeding.

The practitioner must justify the exposure under regulation 11(1)(b) and appropriate weight must be given to the matters set out in regulation 11(2). In doing so, the practitioner is required by this regulation to have particular regard to the urgency of the exposure.

### **Regulation 11(4)**

This regulation is linked to regulation 10(5) which requires the referrer to supply the practitioner with sufficient medical data relevant to the exposure requested, to enable the practitioner to decide whether the exposure can be justified. Regulation 11(4) requires the practitioner to

consider the data provided by the referrer before justification, to avoid any unnecessary exposure.

## 12. Optimisation – Regulation 12

Regulation 12 provides for the optimisation process which involves ensuring that doses arising from exposures are kept as low as reasonably practicable, but consistent with the intended purpose. In practice, optimisation is a process which relies heavily on professional competence and skill.

### **Regulation 12(1)**

Under this regulation, doses arising from all exposures to which the Regulations apply, other than those intended for radiotherapy, must be kept as low as reasonably practicable. For example, diagnostic imaging exposures need to be of sufficient quality to answer the clinical question posed, but the individual should not be exposed to doses beyond this. In practice, decisions on the use of devices or techniques designed to optimise exposures will rest with the practitioner and operator and may depend on factors such as availability or clinical circumstance.

### **Regulation 12(2)**

This regulation requires individual planning of target volumes for all radiotherapeutic exposures. It also applies therefore, to therapeutic research exposures. Doses to non-target volumes and tissues must be kept as low as reasonably practicable and consistent with the intended purpose of the exposure.

The practitioner should use the best means available and decisions on optimisation should be taken to ensure the most appropriate care for each individual patient.

For individual planning regarding therapy with unsealed sources, the practitioner is recommended to carry out an assessment of the individual patient, taking into account any established dosimetry techniques, relevant professional guidance and the patient's overall medical condition. Use of standard activities of radiopharmaceuticals may be appropriate in some cases, where this is consistent with professional guidelines.

### **Regulation 12(3)(c)**

In practice, the requirement to adhere to diagnostic reference levels is with respect to the typical values for a procedure and should not be applied to individual patient procedures, where diagnostic requirements should be applied.

### **Regulation 12(4)**

This regulation requires the employer's procedures to provide certain safeguards for medical and biomedical research programmes.

### **Regulation 12 (4)(c)**

This regulation requires that dose constraints for research exposures where no direct medical benefit for the individual is expected, must be adhered to. The constraint must be set by the employer in procedures, as per Schedule 2(1)(g), and it is recommended that this should be set at a level to facilitate the research, consistent with the research protocol.

### **Regulation 12(4)(d)**

This regulation requires the planning of individual target levels of doses for patients who voluntarily undergo experimental diagnostic or therapeutic practices in cases where some benefit to the patient is expected. It is recommended that the practitioner in such circumstances is identified as the person most able to set these target levels, with respect to knowledge of

ionising radiation and its potential risks. In practice the practitioner may wish to seek advice from others to clarify the doses involved.

In practice, the planned target level of dose should be set so the benefit outweighs the detriment, so as to avoid excessive doses to non-target volumes or organs at risk. For example, where interventional techniques are employed, a radiation dose target level should be set below that which might produce unacceptable levels of skin damage.

### **Regulation 12(5)**

This regulation requires that the employer establishes guidance for carers and comforters. It is recommended that this guidance should provide practical information regarding dose optimisation such that the dose constraint is not exceeded.

### **Regulation 12(6)**

This regulation requires the employer's procedures to provide for the giving of written instructions and information in cases where radioactive substances are administered, if appropriate. The regulation sets out the persons to whom such instructions and information must be given.

Regulation 12(6)(a) refers to the patients themselves where they are adults or children who have capacity to consent to the treatment or diagnostic procedure. It is recommended that in cases where children are subject to exposures it may also be appropriate to give the information or advice to the person(s) with parental responsibility.

Regulation 12(6)(b) deals with circumstances where the patient is a child who lacks capacity to consent. This should be based on the ability of the child to understand information provided rather than age. The regulation requires that the information be given to the person(s) with parental responsibility.

Regulation 12(6)(c) deals with adults that lack capacity and requires that written instructions and information is provided to the person considered most appropriate by the practitioner. In selecting who to give the information to, it may be useful to consider paragraph 7 of Section 4 of the Mental Capacity Act 2005, although it is likely that circumstances will differ considerably for each individual.

### **Regulation 12(7)**

This regulation sets out some of the matters to be addressed in the information to be provided pursuant to regulation 12(6) and when they should be given. In practice, the level of administered activity and resulting dose to others will determine what, if any, advice needs to be given. For example, it will usually be appropriate to give advice in most therapy exposures.

### **Regulation 12(8)**

This regulation requires the practitioner and the operator to have regard to certain factors in the optimisation process. One such factor, in regulation 12(8)(c), is high dose to the individual being exposed. This will be relevant to procedures including, but not limited to, interventional radiology, radiotherapy and some CT scanning, which deliver an increased radiation dose compared to most routine diagnostic examinations.

Another factor, as per regulation 12(8)(d), is potential pregnancy, in particular if abdominal and pelvic regions are involved. In practice, the dose to the uterus, and, where pregnancy is confirmed, to the unborn child, is likely to vary with the anatomical site exposed and magnitude of the exposure in radiology or administered activity and radiopharmaceutical in nuclear medicine.

Under regulation 12(8)(e), nuclear medicine exposures to individuals who are breast feeding must also be given due regard. [Further guidance is available](#).

### **Regulation 12(9)**

This regulation requires the employer to ensure that a clinical evaluation of the outcome of each exposure, other than exposures to carers and comforters, is recorded, as set out in the employer's procedures. It is recommended that such an evaluation should be accurate and timely, such that it contributes appropriately to the care of the exposed person. In practice clinical evaluation might include the resulting diagnostic findings or therapeutic implications, as appropriate or, in the case of therapy exposures, a clear record that the exposures delivered are consistent with those prescribed, or where these have deviated, the basis for this.

Factors relevant to the patient dose should be included in the record of clinical evaluation, where appropriate, as such information might enable estimation of the effective dose to the individual to be made at a later date, if necessary.

## 13. Estimates of population dose – Regulation 13

This regulation requires the employer to collect dose estimates from medical exposures, and to provide these to the Secretary of State when requested. Information relating to dose estimates from medical diagnostic and interventional procedures, but not therapeutic procedures, is used to estimate population doses.

## 14. Expert advice – Regulation 14

This regulation explicitly requires the employer to appoint, and entitle as an operator, a medical physics expert (MPE). The MPE should be involved, to varying degrees, in every type of exposure. This is consistent with established good practice and previous regulatory requirements.

In practice, the level of involvement of the MPE should be determined by the level of hazard and risk associated with the type of exposure and the amount of benefit expected from the MPE's advice. It is recommended that an MPE is consulted when a new clinical technique involving exposure to ionising radiation is to be introduced, for example to assess potential impact of doses to those subject to exposure.

Regulation 14(3) provides further information on the advice and activities to be provided by the MPE under these Regulations, including to provide advice on compliance with these Regulations, as in regulation 14(3)(i).

An employer may require more than one MPE, depending on the extent of the activities of the radiological installation. The definition of operator includes the MPE and, as such, the scope of practice of each MPE should be defined in the employer's procedures, as in Schedule 2(1)(b).

## 15. Equipment: general duties of the employer – Regulation 15

Regulation 15 sets out general requirements in respect of all equipment, regardless of when it was installed and brought into clinical service.

### **Regulation 15(1)(b) and 15(2)**

These regulations require the employer to keep and make available for inspection an up to date inventory of equipment and specifies what information the inventory must contain. The inventory must be made available, on request, to the relevant enforcing authority.

### **Regulation 15(3)**

This regulation outlines duties on the employer regarding testing of equipment. It is recommended that testing of equipment before clinical use should be undertaken by staff designated and entitled by an appropriate employer for this purpose, and such staff should be considered as operators. In practice, this activity should not be undertaken by individuals acting purely as service engineers of the company installing or maintaining equipment.

### **Regulation 15(6)**

This regulation outlines requirements relating to equipment performance. Guidelines on acceptable performance criteria for equipment, intended to ensure patient safety, have been produced by scientific professional bodies. The employer may adopt these or similar appropriate criteria. Corrective action should be taken at the earliest opportunity if equipment performance does not meet specified criteria. In some cases where equipment is considered defective, it may be necessary to remove the equipment from service, for example where patient safety could be compromised.

## 16. Equipment installed on or after 6th February 2018 – Regulation 16

This regulation is additional to the general requirements for all equipment that are specified in regulation 15 but applies only to equipment installed after these Regulations came into force.

### **Regulations 16(3) – (6)**

These regulations require certain equipment to have various features or devices for the provision or transfer of specific information.

Regulation 16(5) introduces requirements relating to transfer of information to a record of a person's exposure. In practice, this should enable an estimate of the dose to be made for the exposure, from stored data, should it be required.

## 17. Training – Regulation 17

This regulation prohibits any practitioner or operator from carrying out an exposure or any practical aspect without having been adequately trained. Adequate training is that which satisfies the requirements of Schedule 3.

### **Regulation 17(3)**

This regulation allows trainees to participate in practical aspects of an exposure as part of their training, as long as they are appropriately supervised by a person who has been adequately trained. In practice, the nature and extent of the supervision required will depend on the task in question and the level of pre-existing training and experience. The definition of operator in regulation 2 makes it clear that an individual undertaking practical aspects as part of practical training would be considered an operator, unless under the direct supervision of somebody who is adequately trained.

### **Regulation 17(4)**

This regulation requires the employer to keep and have available for inspection an up-to-date record of all practitioners and operators engaged, showing the date on which training was completed and the nature of the training. It is recommended that this should include practical training relating to specific equipment or equipment functionality, such as dose saving devices, where this varies significantly from established functionality or where the practice is not consistent with routine activities associated with a professional role. Induction programmes might be considered as part of training, for example those elements that relate to the employer's procedures and protocols.

In accordance with regulation 2(2), where the employer is concurrently practitioner or operator, the employer must still keep training records.

In practice, training records should be stored in a manner which enables them to be made available for inspections, for example separately from employee's personnel files.

### **Regulation 17(5)**

This regulation makes clear that, where an employer entitles individuals to act as practitioners or operators but those individuals remain employed by another body, for example agency staff, then the second party (in this example, the agency) are responsible for keeping and maintaining up to date records of previous and continuing education and training (which may include local training, as necessary) of the staff supplied by the agency. These must be made available to the entitling employer upon request.

## 18. Enforcement – Regulation 18

This regulation provides for the Regulations to be enforced by the relevant enforcing authority as if they were made under section 15 of the Health and Safety at Work etc. Act 1974 (in Northern Ireland, Article 17 of the Health and Safety at Work (Northern Ireland) Order 1978) and the provisions of the 1974 Act (the 1978 Order in Northern Ireland) regarding enforcement and offences also apply . As explained in the definitions, the enforcing authority is specific to each of the administrations.

## 19. Revocation and transitional provision – Regulation 20

Regulation 20 of these Regulations revokes the Ionising Radiation (Medical Exposure) Regulations 2000 and associated amendment regulations in Great Britain. In Northern Ireland, Regulation 20 of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 revokes the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 and associated amendment regulations. The Medicines (Administration of Radioactive Substances) Regulations 1978 and associated amendments and the Medicines (Radioactive Substances) Order 1978 are also revoked.

Transitional provisions specify that existing certificates held under the Medicines (Administration of Radioactive Substances) Regulations 1978 that are valid on the 6th February are considered to:

- Be a licence until the expiry date specified
- Licence the employer at the installation specified for the purposes and scope detailed on the certificate
- Licence the practitioner at the installation specified for the purposes and scope detailed on the certificate.

After the Regulations are in force this does not prohibit employers and practitioners from applying for licenses under the Regulations at any time.

## 20. Licensing – Schedule 1

This Schedule provides general information of the requirements for applications for licences. Applications will be managed by PHE on behalf of the Licensing Authority. Further details of the application process and requirements can be found in [guidance published by ARSAC](#). For urgent cases, the Regulations allow for the Licensing Authority to follow an alternative process.

Employer applications for licences are subject to a fee. Details of fees are specified in the Schedule.

## 21. Employer's Procedures – Schedule 2

Schedule 2 sets out a list of matters that must be covered in the employer's procedures. The list is not exhaustive but all those matters identified in Schedule 2 are binding.

Some of the matters listed in Schedule 2 require further comment. These are as follows:

### **"(a) to identify correctly individuals to be exposed to ionising radiation"**

*The procedure should specify how an individual is to be identified before an exposure is made and it is recommended that this be positive and active, for example, "what is your name?"*

In practice the procedure should state by whom the individual should be identified, for instance by the operator carrying out the exposure.

### **"(b) to identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice"**

Entitlement of a referrer, a practitioner and an operator will be determined by the employer and will include their scope of practice (that is, the range of tasks that may be undertaken by them).

Those who are entitled under these Regulations as referrer, practitioner or operator could be identified in a variety of ways in the employer's procedures, for example by profession, grade, or individual name. In practice, decisions on who is entitled to act as a referrer, practitioner or operator, and the scope of practice, should be taken at local level and may involve agreement between the employer and the healthcare professionals involved in exposures.

Entitlement and scope of practice should be supported by education and training. In some cases it may be necessary for the scope of practice of an individual to be restricted, for example to act as practitioner for radiographic procedures for extremities, or for exposures of carers and comforters, but not for complex examinations such as interventional procedures. Where one individual takes on more than one role under regulation 2(2), this must be documented in the employer's written procedures and scope of practice specified.

### **"(c) for making enquiries of individuals of child-bearing potential to establish whether the individual is or may be pregnant or breast feeding"**

It is recommended that such procedures include the location of the primary beam in relation to the abdomen and the age range of individuals who should be asked about pregnancy or breast feeding. In setting this age range, consideration should be given to the increased period of reproductive capacity due to earlier maturity and advances in technology.

### **"(i) 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"**

The amount of information and the methods of conveying information should be commensurate with the associated risk. Posters, leaflets and information provided directly by a professional can all be useful in fulfilling this requirement.

Providing information regarding benefits and risks of an exposure can be difficult and patients and others may respond to information in different ways. It is recommended that information is provided in a simple, succinct and qualitative, rather than quantitative manner, and where possible, includes the clinical context. For example, *"we believe the risks of the procedure are small and the procedure will help us to address your suspected clinical condition through diagnosis and treatment, where appropriate"*.

In some cases, such as interventional radiology, procedures carry other risks, which are not related to ionising radiation. While these Regulations do not address these risks, it may be appropriate to discuss benefits and risks in a comprehensive manner, explained in a clear way so that the patient is aware of the risks associated with each element of the procedure.

In practice, the person who provides information about benefits and risks may differ depending on the clinical scenario. As such, it is recommended that the employer's procedures indicate who should be available to provide this information in a range of scenarios, and that the provision of information should be clearly recorded.

It is not expected however, that this requirement will extend or replace any separate requirements for informed consent processes. Informed consent is not addressed in these Regulations.

**"(n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters"**

It is recommended that such guidance includes, for example, information to identify when carers and comforters should be used to support exposures and how doses can be minimised.

## 22. Adequate Training – Schedule 3

Schedule 3 sets out details of the training which a practitioner or operator must have successfully completed, as relevant to their functions or area of practice, in order to be permitted to carry out medical exposures or practical aspects under the Regulations:

- Table 1 sets out subjects relevant to an individual's functions as practitioner or operator
- Table 2 details subjects relevant to specific areas of practice.

Not all the subjects listed in Schedule 3 have to be covered. The subjects of Schedule 3 that would need to be covered will depend on the range of exposures the practitioner or operator intends carrying out.

The Regulations do not require the referrer to be adequately trained. Nevertheless, there is a requirement for referrers to understand their duties as specified under regulation 10 and to comply with employers' procedures as in regulation 6(2).

## 23. Consequential amendments – Schedule 4

The Regulations include consequential amendments to existing regulations addressing the justification of types or classes of practice, human medicines and occupational exposure to ionising radiations. Schedule 4 sets these out.

The Justification of Practices Involving Ionising Radiation Regulations 2004 address the justification of types or classes of practices and were intended to implement a previous Basic Safety Standards Directive (96/29/Euratom). Regulation 21 ensures that the provisions, relating to a new class or type of practice involving ionising radiation or a class or type of practice which is no longer justified, do not prevent individual exposures which have been justified in accordance with regulation 11 of the Ionising Radiation (Medical Exposure) Regulations 2017.

The Human Medicines Regulations 2012 consolidate instruments concerning medicinal products for human use. Regulation 214 allows operators to administer prescription only medicines which are administered in connection with a medical exposure, if certain conditions are met. The amendments provide that the conditions which must be met relate to adherence to procedures and protocols in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations 2017 and licenced practitioners, as described in regulation 5 of these Regulations.

The Ionising Radiations Regulations 2017 (in Northern Ireland the Ionising Radiations Regulations (Northern Ireland) 2017) address occupational exposures to ionising radiation and include requirements relating to carers and comforters and to equipment used in medical exposures. This amendment removes these requirements from the Ionising Radiations Regulations 2017 as they are now addressed in these Regulations.