

## **The Diagnostic Radiographer as the entitled IR(ME)R Practitioner.**

### **Background**

The Ionising Radiation (Medical Exposure) Regulations 2000 (Great Britain) <sup>1</sup>, (IR(ME)R) and the Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2000<sup>2</sup> (IR(ME)(NI)R) came into force in 2000/2001, in concordance with the European Directive 97/43/Euratom (The Medical Exposures Directive, 1997)<sup>3</sup>. The GB Regulations were amended in 2006<sup>4</sup> and 2011<sup>5</sup> and in 2010<sup>6</sup> for NI. Of course, the new IR(ME)R 2017<sup>7</sup> and IR(ME)R (NI) 2018<sup>8</sup> will come into force on 6<sup>th</sup> February 2018 in concordance with the European Council Directive 2013/59/Euratom<sup>9</sup>. The Society & College of Radiographers (SCoR) considers this is an ideal opportunity for IR(ME)R Employers (and Radiography Departments) to re-evaluate the governance processes around the regulatory framework. This document will forthwith concentrate on the new UK Regulations bringing together both the GB (2017) and NI (2018) Regulations.

IR(ME)R 2017 identifies four duty holders, each of whom has clearly identified responsibilities under the Regulations: the Employer, Referrer, Practitioner and Operator. The Employer has a number of legal obligations including establishing a framework of **written procedures** (Regulation 6(1) / Schedule 2) and protocols under which the duty holders work, as well as entitling the duty holders for the tasks they may perform under IR(ME)R. The Employer is normally considered to be the Chief Executive Officer, however the task of leading on IR(ME)R matters may have been delegated to an alternative individual who should be of sufficient seniority (e.g. at Board level). It is imperative that all duty holders know who the IR(ME)R Employer is for their area of practice.

One of those duty holders is the **IR(ME)R Practitioner**, whose sole role it is to justify a medical exposure (before it takes place) using the clinical information received by the Referrer (Regulation 11(b)). SCoR recognise that Radiographers may already possess the skills to be entitled as a Practitioner within the individual's scope of practice but also believes that many Radiographers who think they are entitled IR(ME)R Practitioners for their practice are, in fact, probably acting as the IR(ME)R Operator using Authorisation Guidelines issued by an IR(ME)R Practitioner (Regulation 11(c)). The latter practice is relevant and supports a seamless patient journey but it is important that each Radiographer recognises which duty holder role he/she undertakes at each part of that journey, is fully aware of the tasks and responsibilities for each part and can prove adequate training for each role.

### **Purpose of Guidance**

This SCoR guidance illustrates the importance of proving "adequate training" according to Schedule 3 of IR(ME)R 2017 before a Radiographer is entitled as an **IR(ME)R Practitioner**. It is not meant to be prescriptive as the responsibility for IR(ME)R compliance still rests firmly with the Employer. SCoR is grateful to Holly Warriner, IR(ME)R Inspector at the Care Quality Commission for bringing this issue to our attention. Although, this guidance focusses on the Radiographer role, the subject matter may also be useful for employers before entitling any other healthcare professional (e.g. a Radiology Registrar). The guidance suggests standard minimum requirements for employers to consider (and assess) before entitling an individual as a Practitioner under IR(ME)R 2017. Having a "Standard" enables service leaders to benchmark training and competencies for the purpose of IR(ME)R

governance, compliance and assurance. The guidance establishes a base-line for development into a training framework which should also include more specific detail in relation to the area of practice and patient pathway concerned. It provides assurance to patients and referrers that the individual undertaking justification of the request for an investigation involving ionising radiation is adequately trained and competent to do so. Please note, SCoR understands that there is a wide variety of practice across the UK in the entitlement of Radiographers and other individuals as IR(ME)R Practitioners. This guidance is meant to support practice for the benefit of the patient and not to hinder already effective and safe practice.

### Guidance

For the purpose of IR(ME)R 2017 & IR(ME)R NI 2018, the Practitioner is defined as a registered health care professional, within the meaning of section 25 (3) of the National Health Service Reform and Health Care Professions Act 2002(a)<sup>10</sup>.

It is important to clarify at this stage that the term IR(ME)R Practitioner is not to be confused with Radiographer practitioner used to describe job title or College of Radiographers (CoR) career progression level<sup>11</sup>. It is equally applicable to those working with ionising radiations in diagnostic and therapeutic radiology within the UK NHS and Independent Sector.

Regulation 11 of IR(ME)R 2017 details the legal requirements around justification of individual exposures including the need for a Practitioner Licence when delivering nuclear medicine exposures. The IR(ME)R Practitioner should be able to show a net benefit referring to the following matters:

- the specific objectives of the exposure and the characteristics of the individual involved;
- the total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure;
- the individual detriment that the exposure may cause;
- the urgency of the exposure; and
- the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

To perform the action of justification, the request for the exposure is assessed against the clinical data supplied by the IR(ME)R Referrer (Regulation 10(5)). The IR(ME)R Practitioner must have had adequate training and be competent to consider the potential detriment of the exposure against the potential benefits for that individual.

The Employer should specify the scope of practice for which an individual can act as an entitled IR(ME)R Practitioner. The scope of practice should clearly define the range of procedures the individual is entitled to justify. Any exclusions should be clearly documented for example minimum patient age or investigations involving contrast agents. It is also the IR(ME)R Practitioner's responsibility (in conjunction with the IR(ME)R Operator) to ensure that the radiation dose to the patient is as low as reasonably practicable.

### **Adequate training to be an IR(ME)R Practitioner**

IR(ME)R Practitioners must have successfully completed training, including theoretical knowledge and practical experience as are relevant for their functions and for their area of practice as detailed in Schedule 3 of IR(ME)R 2017. Areas of training need only reflect the tasks that the duty holder will undertake.

The subject areas in Schedule 3, Table 1, as relevant to the IR(ME)R Practitioner role, should be covered in adequate breadth and depth so that an individual may function optimally in their role. Table 2 details areas of knowledge and training relevant to specific areas of practice (diagnostic radiology, radiotherapy and nuclear medicine). Pre-registration Radiography education and training will have provided much professional education and practical training (Regulation 17(2)), however, there will be much scope for further development in many of these areas and there will be a clear need for supplementary training in some of them. When an individual Radiographer receives CoR Accreditation as an Advanced Practitioner or Consultant level Radiographer, SCoR firmly states that this individual has proven clinical expertise in his/her field of practice – this will have involved education and training at Masters / Doctorate level.

SCoR considers that an individual may be considered for the role of the IR(ME)R Practitioner, if, in their own right, they have the underpinning knowledge and skills to be able to perform an intellectual evaluation of sufficient net benefit with due regard to risk of the intended exposure (the risk versus benefit analogy).

SCoR believes that the skills to be an entitled IR(ME)R Practitioner should include knowledge of the biological and detrimental effects of ionising radiation associated with clinical imaging procedures – these include stochastic, essentially cancer induction and deterministic effects, (tissue reactions) mainly skin burns and cataract formation.

In addition the following skills are also required but are not restricted to:

- Understanding the clinical details including all medical terminology, abbreviations and anatomical and physiological references.
- Understanding if the investigation will have an impact on the future management of the patient.
- Understanding the clinical question and assessing the most appropriate investigation.
- Understanding and considering appropriate alternative investigations that may or may not involve ionising radiation.
- Knowing when and how to communicate with the IR(ME)R Referrer if further clinical information is required.
- Understanding and compliance of the procedure for notifying the IR(ME)R Referrer of unjustified examinations.
- Knowledge and understanding of previous imaging including thorough search mechanisms for relevant radiological investigations that may have occurred elsewhere.
- Understanding of the risk of the exposure to the patient<sup>12</sup> and the method by which this is communicated to the patient in line with the Employer's procedures (Schedule 2(i)).
- Ensuring that the patient, where relevant, is provided with adequate information relating to the benefits and risks of the exposure before it takes place (Schedule 2(i)).
- Understanding the potential risk to the patient of the investigation not being performed.
- Understanding the patient's fitness to consent to, tolerate and comply with the procedure.

- Thorough knowledge and compliance of the Employer's procedures with regard to correct identification and recording of the protocol the IR(ME)R Operator is directed to follow.
- Collaboration with the IR(ME)R Referrer and Operator to ensure optimisation of the individual exposure in accordance with the principle of As Low as Reasonably Practicable consistent with the intended purpose.
- In addition: the IR(ME)R Practitioner must pay special attention to medical exposures falling under Regulation 11(3) which include those involving:
  - children
  - health screening programmes
  - carers and comforters
  - asymptomatic individuals
  - those in whom pregnancy cannot be excluded
  - individuals who are breastfeeding and involve the administration of a radioactive substance

Before IR(ME)R Practitioner entitlement is given, an assessment of the aforementioned skills should be undertaken – [Appendix I](#) details a sample assessment that SCoR considers useful. The task of assessment, which should be undertaken by an entitled IR(ME)R Practitioner, may be delegated by the Employer to another but the responsibility for ensuring adequate training still rests with the Employer. It must be stressed that the assessment is not merely a set of listed competencies but involves the provision of evidence of knowledge and understanding. If an individual is already CoR accredited for his/her scope of practice, and that accreditation is still current, then adequate training may already be assumed. This, however, does not mean that an assessment should not take place.

Entitlement by the Employer should be given to each individual in writing and should be clearly annotated in the Employer's Procedures (Schedule 2(b)) whether as a group of professionals or as individual names. There is a requirement (Regulation 17(4)) for training records to be documented and available for inspection and this is especially pertinent as and when new technologies are implemented. [Appendix II](#) provides a link to a useful "justification" flow chart developed by the International Society of Radiographers and Radiologic Technologists<sup>13</sup>

SCoR considers that those individuals entitled to act as IR(ME)R Practitioners should undertake regular audit of their practice to ensure standards are maintained and that there should be a written procedure for that audit. IR(ME)R Practitioners should record and reflect upon discrepancies in line with employer's procedures. Of course, scope of practice can and does evolve and should be assessed and updated regularly. There should also be a written procedure to follow if the IR(ME)R Practitioner does not meet the standard. The procedure should detail provision for re-assessment and implementation of a suspension period if necessary.

## Appendix I

**Sample Assessment** – adapted with kind permission from University Hospitals Coventry and Warwickshire NHS Trust

The assessment could be undertaken in two parts – a discussion and a practical element. Both parts should ensure the development of evidence to include a measurement of relevant and current knowledge. It is further assumed that the individual will undertake continuous professional development relevant to their role and “registration” status.

### Part 1 – Discussion

To involve a discussion with the assessor ensuring a deep knowledge of:

- all aspects of all clinical imaging examinations within the individuals’ scope of practice
- the relevant local referral guidelines with associated evidence base
- where to find previous imaging examinations
- when alternative examinations not using ionising radiations should be stipulated
- the theory of radiation dose & measurement
- the local Employer’s procedures relevant to the IR(ME)R Practitioner role

### Part 2 – Practical

To involve a practical (with a **pass mark of 80%**) to include:

- a review and audit of previous IR(ME)R Practitioner scenarios including a range of 10 previous clinical image requests and subsequent examinations to check that justification took place correctly (i.e. the image did answer the clinical question and did inform ongoing patient management). This review should detail *the clinical question; the imaging modality; the patient’s status*. The range of examinations in this review should include aspects relevant to the individuals’ scope of practice e.g. patient age; pregnancy status etc)
- an assessment of 25 random request cards for the individual and to justify (or not) – these requests should include a range of clinical questions, types of examinations and patient conditions that is aimed to be included in the individuals’ scope of practice.

## Appendix II

### **Justification Flow Diagram**

<https://www.isrrt.org/justification-flowchart>

## References

1. The Ionising Radiation (Medical Exposure) Regulations 2000, Statutory Instrument No. 1059. London, UK: HMSO 2000. <http://www.legislation.gov.uk/uksi/2000/1059/made>
2. The Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2000 [http://www.legislation.gov.uk/nisr/2000/194/pdfs/nisr\\_20000194\\_en.pdf](http://www.legislation.gov.uk/nisr/2000/194/pdfs/nisr_20000194_en.pdf)
3. The European Directive 97/43/Euratom <https://publications.europa.eu/en/publication-detail/-/publication/aa7564fa-fd07-4872-943c-66df8f4f1099/language-en>
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6. The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010, Statutory Rules of Northern Ireland No. 29. <http://www.legislation.gov.uk/nisr/2010/29/made> (accessed 6th January 2015)
7. The Ionising Radiation (Medical Exposure) Regulations 2017 <http://www.legislation.gov.uk/uksi/2017/1322/contents/made>
8. The Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2018 (unpublished)
9. European Commission (2013), Council Directive 2013/59/Euratom, 2013. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:013:0001:0073:EN:PDF>
10. The National Health Service Reform and Health Care Professions Act 2002(a) <http://www.legislation.gov.uk/ukpga/2002/17/contents>
11. The College of Radiographers (2013), Education and Career Framework for the Radiography Workforce <https://www.sor.org/learning/document-library/education-and-career-framework-radiography-workforce>
- 12 Public health England (2014), Exposure to ionising radiation from medical imaging: safety advice <https://www.gov.uk/government/publications/ionising-radiation-from-medical-imaging-examinations-safety-advice/exposure-to-ionising-radiation-from-medical-imaging-safety-advice>
13. The International Society of Radiographers and Radiologic Technologists <https://www.isrrt.org/role-justification>