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THE SOCIETY & COLLEGE
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Ionising Radiation (Medical Exposure) Regulations 2017; briefing for radiographers who undertake commenting or reporting

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Contents

Executive Summary	3
Clinical Evaluation	3
Entitlement	4
Operator	4
Training	5
IR(ME)R Procedure	5
References	6

Executive Summary

The *Ionising Radiation (Medical Exposure) Regulations 2017*¹ and the *Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2018*², hereafter jointly referred to as *IR(ME)R*, came into force on 6 February 2018. These regulations implement some provisions of the *European Council Directive 2013/59/Euratom*.³

IR(ME)R 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 and protocols under which the duty holders work, as well as entitling the duty holders to perform tasks 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.

Regulation 12(9) of IR(ME)R requires the Employer to ensure that a clinical evaluation of each exposure outcome is recorded, with the exception of exposures to carers or comforters, and to set out in a written procedure how, and by whom, this evaluation is to be done.

The Department of Health *Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017*⁴ advises that, in practice, clinical evaluation might include diagnostic findings, therapeutic implications or a clear record that therapeutic exposures delivered are consistent with those prescribed, or reasoned decisions for not doing so.

Clinical Evaluation

A clinical evaluation record should include factors relevant to patient dose, where appropriate. It is important to note that if no evaluation of an exposure will be carried out, then that exposure cannot be justified and therefore should not be undertaken. Clinical evaluation is an Operator function under *IR(ME)R*. This person must be appropriately trained and entitled accordingly by the Employer.

The clinical evaluation of an exposure is normally, but not always, recorded via the radiology report. It can be made directly into the patient record or on the Picture Archiving and Communication System (PACS). The evaluation may be carried out by anyone who is appropriately trained and assessed as competent; this may be radiologists, radiographers, medical clinicians, or other healthcare professionals; however, they must be adequately trained and entitled as an Operator for this purpose. Where the report is recorded will depend on local circumstances. The report should be produced in a timely fashion to allow further appropriate patient management. The process of making, recording, and expediting (where necessary) a clinical evaluation for each exposure should be clearly described in the Employer's written procedures. More information is available in *Standards for interpretation and reporting of imaging investigations*.⁵

Entitlement

Entitlement by the Employer means that permission has been given to act, in compliance with the Regulations, according to the specific responsibilities of a duty holder role (i.e. Operator). There must be a documented entitlement process within the Employers' procedures detailing the mechanism through which an individual becomes entitled.

As part of the entitlement, the Employer must check that adequate training is achieved and link this to the scope of practice and tasks that an individual can carry out before entitlement is given. It is important to note that the Employer must be able to demonstrate that the Operator is adequately trained (*Regulation 17(1) (2)*) to undertake such tasks and undertakes continuing education and training (*Regulation 6(3)(a),(b)*).

Where reporting services are undertaken by a third party (outsourced), the Employer must be assured that the individuals performing this role have been entitled as IR(ME)R Operators. If the Employer entitles a group of individuals as Operators to undertake clinical evaluation, the Employer must satisfy themselves that each individual has been adequately trained and assessed as competent to perform the task.

An Operator who is a registered health care professional may also be entitled, in accordance with the Employer's procedures, as an IR(ME)R Referrer to refer individuals for exposure to a Practitioner. For Operators who are not medically trained this is likely to be for specific examinations and detailed within a defined scope of practice.

An example of the process of entitlement could involve the distribution of a signed letter detailing the specifics of that entitlement; in terms of image interpretation and reporting, this could include a table of radiology procedures that the individual is deemed competent and entitled to evaluate (report). Entitlement could be considered as providing a safety check for both the Employer and the individual, in that the Employer is confident in the ability of the individual. In terms of *IR(ME)R*, no Operator may carry out a task for which they have not been trained and entitled, and similarly they cannot be asked to do so.

Operator

The definition of the IR(ME)R Operator is 'any person who is entitled, in accordance with the Employer's procedures, to carry out practical aspects'.

Practical aspect means the **physical conduct of a medical exposure and any supporting aspects, including clinical evaluation**. Operators are legal duty holders who have been entitled by the Employer to carry out practical aspects of a medical exposure. These include the clinical evaluation of an exposure (i.e. the interpretation and reporting of the image).

Training

Individuals entitled to act as an Operator must have undergone training in subjects that are relevant to their functions, as detailed in Tables 1 and 2 of *Schedule 3*. The Employer must be satisfied that the individual has undergone adequate training and is competent to carry out the tasks at the point of entitlement. Adequate training is a requirement of any entitled individual who evaluates clinical images (e.g. doctors, nurses, radiographers, and other healthcare staff). Similarly, there is an obligation placed on Operators to not carry out any practical aspect unless they have been adequately trained (*Regulation 17(1)*).

It is the Employer's responsibility to maintain documented and up-to-date evidence of "adequate training" for all entitled IR(ME)R duty holders (*Regulation 17(4)*). Training records should reflect relevant education and training, including continuing professional development and local department-specific training, as well as that achieved through additional external qualifications and courses.

IR(ME)R Procedure

To avoid lengthy descriptions of different staff groups at different levels of training / competency having to be included in a procedure, it may be helpful to simplify the IR(ME)R procedure relating to clinical evaluation by including a statement such as the following:

Image interpretation and reporting (known as clinical evaluation under IR(ME)R) can only be carried out by an adequately trained, competent Operator who has been entitled to do so by the Employer. A trainee can undertake image interpretation and reporting under the supervision of a competent entitled Operator who is responsible for the task being completed correctly. A matrix of image interpretation and reporting tasks and entitled Operators is held and maintained by the Clinical Director of the imaging department.

References

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5. The Royal College of Radiologists. 2018. Standards for interpretation and reporting of imaging investigations. Second edition. London: The Royal College of Radiologists. Available at https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr181_standards_for_interpretation_reporting.pdf [accessed 28.06.2019]



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