As of 1st October 2024, amendments to the Ionising Radiation (Medical Exposure) Regulations 2017 have come into force. One purpose of the 2024 amendments is to correct errors made in the 2018 amendment document, whilst also introducing new regulations, procedures and definitions

Most of the regulations remain unchanged. However, there are two new requirements in Schedule 2, Employer's Procedures that will need to be addressed by all employers. There are new regulations for collaborative working and the establishment of dose reference levels in radiotherapeutic practice. Amendments have been made to regulation 12 relating to radioactive substances that accommodate the different legal statutes regarding an individual's mental capacity and consent that are enforceable in England, Wales and Scotland.

A basic outline of the key changes are described in this article.

Regulation 6A- Cooperation between Employers

There is a new regulation, 6A. This will be significant for any two or more employers that might share involvement in the exposure of an individual to which the IR(ME)R17 regulations apply. For example, in the common scenario of a GP practice referring for X-ray imaging to the local general hospital, both parties will be legally beholden to co-operate with the exchange of information. The extent of this should be such that it enables each Employer to comply with the IR(ME)R17 regulations. Any lack of cooperation that compromises this ability could be deemed an enforceable contravention under 6A. During audit the CQC will be looking for evidence of procedures in which the required level of cooperation between parties is agreed and records to show that effective cooperation is taking place.

Regulation 12 - National differences relating to the administration of radioactive substances for treatment or diagnosis

As a legal instrument, the IR(ME)R17 regulations are applicable within England, Wales and Scotland. As such the arrangements must be drafted to cover situations where different laws are in place within Great Britain (note that an equivalent, but separate set of IR(ME)R laws are enforced in Northern Ireland). The need to accommodate such differences has been recognised in the amendments with respect to regulation 12, the administration of radioactive substances for treatment or diagnosis (reg. 12(6)) and the provision of written instructions and information that inform consent.

The 2024 amendments have the consequence that all patients aged 16 years and above, regardless of mental capacity are considered as adult. They also accommodate the differences in statutes covering mental capacity in England & Wales and Scotland.

As previously, consent for the exposure of children (persons below the age of 16 years) would be sought from those with 'parental responsibility', as defined in the respective Acts relating to children in England & Wales and Scotland. It is noteworthy that the amendments now recognise 'The Age of Legal Capacity (Scotland) Act 1991'. This enables those in Scotland under 16 years to directly consent to a medical procedure, if judged capable by the medical practitioner. There is no equivalent statute in English & Welsh law, albeit the 'Gillick competence' stands as legal precedent in these nations and provides children considered of sufficient maturity the legal protection to consent to their own treatment.

The 2024 amendments have much simplified how employers seek consent for patients who

may lack capacity that are either 16 or 17 years of age. Previously (see regulation 12.(6)(b)), there was a specific requirement applicable to this age range to determine who may act with 'parental responsibility' with respect to the Children Act 1989. Following the amendments, all recourse to the Children Act has been removed and the procedure for providing information and seeking consent for a patient lacking capacity that is either 16 or 17 is the same as for all adults. In England & Wales the amendment references the Mental Capacity Act 2005, where a person that has reached 16 years is deemed an 'adult'. In this situation the IR(ME)R operator (note, this has changed from the IR(ME)R practitioner) should seek consent from 'the most appropriate person'.
Because the Mental Capacity Act 2005 is not part of Scottish law, another amendment is required to accommodate the treatment of adults in Scotland. This references the 'Adults with Incapacity (Scotland) Act 2000'. As in the Mental Capacity Act, those that have reached 16 are considered as 'adult'.

Regulation 12 - Establishment of Dose Reference Levels in radiotherapeutic practice

The term 'dose reference level' has been introduced. This is to facilitate a new requirement to establish dose reference levels for typical localisation or verification procedures performed as part of radiotherapeutic practice. Inevitably 'dose reference level' will be abbreviated to DRL, which is the same acronym already used in diagnostic imaging, where the 'D' of DRL is a 'diagnostic' reference level. However, this shouldn't be as confusing as it might seem, as a DRL, be it a dose or a diagnostic reference level will effectively represent the same concept.
An example of where DRLs are now required would be for CT planning exposures as part of radiotherapy treatment.
This requirement has been added to regulation 12, see 12(3)(d).

Definition of Individual Detriment

A definition of 'individual detriment' has been added to regulation 2 'Interpretation'. The concept of assessing an individual's detriment from exposure to ionising radiation is fundamental to the function of the IR(ME)R practitioner and their ability to justify exposure. [see regulation 11(2)(c)]. The interpretation describes individual detriment as,

> *'clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance'*

This definition encompasses the whole scope of possible detriment, including what we might already be familiar with referring to as 'early' and 'late' effects. 'Early' being those deterministic injuries that will present with certainty at known dose thresholds (e.g. skin burn). 'Late' effects, being primarily the consequential induction of cancer, the presentation of which would be delayed, and the likelihood is determined by probability (stochastic effects).

Regulation 15 - Inventory of 'Equipment that is Software'

Regulation 15 is concerned with equipment and the associated duties of the employer. This has always required that the employer keep an inventory of the radiological equipment under their control. The regulation specified a minimum amount of information regarding each device to be recorded. The 2024 amendments have added a new category, 'equipment that is software'. An inventory of all such software equipment must be kept, each with a list comprising details of the software company, brand name, current software version, year of original installation and year of current software version installation in clinical use. The wording of the new regulation implies that an inventory of 'equipment that is software' would be limited to standalone software packages, such as GE Xeleris (nuclear medicine) or a radiotherapy planning system. Software used by computers for the control of radiological devices and their sub-systems would not be classed as standalone equipment and therefore, barring any future clarification from the CQC, need not be included in the inventory at this point.

See regulation 15(2A).

New requirements in SCHEDULE 2, Employer's Procedures

Although IR(ME)R17 has always required that clinical audit be carried out (regulation 7), it is now listed amongst those processes for which the employer must have a procedure.

Also new is the requirement for the employer to have a procedure 'for making, amending and cancelling any referrals for exposure'. This is a direct consequence of the CQC's analysis of reportable incidents where the failure to cancel examinations no longer required has been identified as the root cause of a trend in a significant proportion of accidental or unintended additional exposure. Going forward, the implementation of a local procedure for managing referrals will be a predictable line of inquiry from a CQC inspector during an audit of radiology services.

See SCHEDULE 2 Employer's Procedures (o) and (p).

Removal of Regulation 6(6)

And finally, the 2024 amendments have removed a curiosity from IR(ME)R17, which was the requirement set out in regulation 6(6) whereby the employer was to establish a general dose constraint in terms of individual dose (either effective or equivalent) over a defined, appropriate, period of time.
As a general principal this was always counter to the primary intention of IR(ME)R, impossible to implement and generally would have been ignored. Its original inclusion could generously be attributed as an oversight, so its official removal is welcome.

In summary the key take-aways are:

- Additional Schedule 2 Employer's Procedures required for Clinical Audit and Management of Referrals
- Dose reference levels required for localisation and planning procedures associated with radiotherapeutic practice

- A new regulation, 6A, that requires employers to cooperate when they share responsibility for exposure of an individual
- Compilation of inventory comprising details of ‘equipment that is software’
- Need for review of procedures for providing instructions and information for radiopharmaceutical procedures with respect to obtaining consent for those in the 16 to 17 age range.