Medical Exposures Group Update

E-bulletin #1 September 2024

Welcome to the first Medical Exposures Group (MEG) E-bulletin, which provides an update on changes to the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) in Great Britian. Find this, and future editions of the **MEG E-bulletin** on our website.

Please email **medicalexposures@ukhsa.gov.uk** for advice on compliance with IR(ME)R.

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)

IR(ME)R is legislation aimed at the protection of the patient against the hazards from ionising radiation. IR(ME)R establishes a safety framework and places duties on the employer and healthcare professionals including the requirement that accidental and unintended exposures are reported to the relevant UK healthcare regulators. There are separate IR(ME)R regulations for Great Britain and Northern Ireland. A post implementation review has been completed on IR(ME)R in Great Britain.

Post Implementation Review (PIR)

In the UK, it is a legal requirement for secondary legislation, such as IR(ME)R to include a statutory review.

PIRs aim to review regulations at timely intervals to assess their effectiveness, whether they are still necessary and whether they are having the intended effects following implementation and during their operation.

Five years after implementation, the regulations were reviewed to understand if IR(ME)R:

- has achieved its original objectives,
- has resulted in any unintended effects,
- has objectives which are still valid,
- is still required and remains the best option for achieving those objectives,
- can be improved to reduce the burden on business and its overall costs.

A light touch consultation process was conducted with formal feedback sought from stakeholders. The **PIR** was published in 2023 and found that the regulations have been successful in introducing formal recognition on medical physics experts (MPEs) and streamlining the licensing system. The PIR also found that the regulations provide sufficient latitude for employers to adopt processes and procedures that meet the requirements of the regulations. No significant concerns were demonstrated, but the PIR identified some minor concerns which would be addressed through amendments to IR(ME)R.

The Ionising Radiation (Medical Exposure) Amendment Regulations 2024

The **amendment regulations** were laid before parliament on 3 September 2024 and come into force in England, Scotland, and Wales on 1 October 2024.

The scope of the regulations has been extended so all the provisions which applied to medical exposures now also apply to non-medical imaging exposures. Further changes are summarised below.

Updated definitions	
Accidental exposure	consistent with **SAUE guidance**
Equipment	includes software which directly assists an operator in carrying out a clinical evaluation
Non-medical imaging exposure	includes "using medical radiological equipment"
Practical aspect	removes "maintenance" in relation to equipment
New definitions	
Clinical evaluation	means interpretation of the information resulting from an exposure, including the outcome and implications
Dose reference levels	means dose levels in radiotherapeutic practices for typical localisation or verification exposures for groups of standard-sized individuals or standard phantoms for broadly defined types of equipment
Relocated definitions	
Ethics committee, Individual detriment	No change, moved from regulation 11 to regulation 2
Radiation Protection Adviser, Radioactive Waste Adviser	No change, moved from regulation 14 to regulation 2
Removed definitions	
Evaluation	Removed. See new definition for "clinical evaluation"

Employer responsibilities - changes to regulations 6, 7, 8 and 15

The employer (regulation 6) must:

- establish referral guidelines for all types of exposures,
- have regard to international and **national diagnostic reference levels** or local dose surveys when setting local diagnostic reference levels,
- regularly review and make available to an operator, dose reference levels having regard to international and **national dose reference levels** and local dose surveys where available,
- carry out reviews of both diagnostic reference levels or dose reference levels when they are consistently exceeded and make sure that corrective action is taken where appropriate.

In addition, the employer must take appropriate actions based on the results of clinical audit (regulation 7) and analyses of actual and potential accidental or unintended exposures (regulation 8).

The equipment inventory held by the employer (regulation 15(2A)) should be updated to include information on software used to directly assist an operator in carrying out a clinical evaluation. This must now include:

- name of software company
- brand name
- current software version
- year of original installation
- year of current software version installation in clinical use

Interventional Radiology and CT equipment must inform the operator of relevant dose factors (regulation 15(5)) – previously the practitioner had to be informed.

Employer's procedures – schedule 2

Two new employer's procedures are required: EP(o) for carrying out clinical audit and for any appropriate action to be taken and EP(p) for making, amending, and cancelling referrals. The employer's procedure for the use and review of diagnostic reference levels now also includes the same requirements for dose reference levels (EP(f)).

Co-operation between employers - new regulation 6A

Where two or more employers work together to carry out exposures or any practical aspects, refer for exposures or justify exposures, co-operation between employers is required to share information, so that they can each comply with the requirements of IR(ME)R. It is important to agree the roles and responsibilities of each party.

Clarification on consent for individuals lacking capacity or competence – regulation 12

The requirements around research exposures (regulation 12(4)) have been updated to include situations where consent to take part in the trial is given by a representative of the trial participant.

IR(ME)R now includes references to competence and capacity as this applies differently in Scotland compared to England and Wales. This has led to updates to regulation 12(6), where written information should be given to patients who are administered with radioactive substances. The information should be given to:

- the patient, where they have capacity or competence to consent to the procedure,
- the person with parental responsibility, if the patient is a child under 16 and lacks capacity or competence to consent to the procedure,
- the most appropriate person, if the patient is 16 or older and lacks capacity or competence to consent to the procedure.

The requirements around the contents of the written information have not changed. This should include how to restrict doses to the patient and others and the associated risks. The information should be provided before the patient leaves the hospital or site.

Expert advice – regulation 14

The matters to which the MPE must contribute to have been updated to include the application of dose reference levels in relation to optimisation of radiotherapy imaging exposures. The MPE must also provide training for operators as well as practitioners and other staff.

Licence fees – schedule 1

The fees for licence applications have been increased in line with inflation.

Licence application type	Original fee	New fee
Employer - new	£250	£298
Employer – amendment	£200	£244
Employer – renewal	£200	£244
Employer – notification	£0	£0
Practitioner - any	£0	£0

Training - schedule 3

The schedule has been updated to improve formatting and layout of tables 1 and 2 which describe adequate training. Table 1 now includes:

- Dose reference levels,
- Quality assurance for written procedures and written protocols,
- Quality control for the routine inspection and testing of equipment,
- Proactive use of clinical audit,
- Analysis of events involving accidental or unintended exposures,
- Study of risk of accidental or unintended exposures.

Quality assurance, and Quality control including routine inspection and testing of equipment, have been removed from Table 1.

Table 2 has been updated to rationalise and streamline the training requirements. The section on all modalities now includes equipment specification and a section on contrast media. Each modality now has consistent sub-headings:

- General,
- Specialised techniques,
- Practical aspects.

Radiotherapy also includes radiobiological aspects and specific radiation protection requirements. Nuclear medicine also includes molecular radiotherapy, radiopharmaceuticals, and specific radiation protection requirements.

Updates to guidance

The Department of Health and Social Care have published **guidance** on IR(ME)R. The Clinical Imaging Board and Radiotherapy Board plan to review their guidance on the implications of IR(ME)R for clinical practice to include the new requirements of the amendment regulations.

Updated SAUE notification guidance

CQC, HIS, HIW and **RQIA** have updated their guidance for employers and duty holders for notifying significant accidental and unintended exposures under IR(ME)R. This replaces previous guidance and will shortly be available on all enforcing authorities' websites.

Links to relevant publications
IR(ME)R explanatory memorandum
Post Implementation Review report