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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations, together with the Ionising Radiations Regulations 1999 (S.I.1999/3232) partially implement, as respects Great Britain, Council Directive 97/43/Euratom (OJNo. L180, 9.7.97, p.22) laying down basic measures for the health protection of individuals against dangers of ionising radiation in relation to medical exposure. The Regulations impose duties on those responsible for administering ionising radiation to protect persons undergoing medical exposure whether as part of their own medical diagnosis or treatment or as part of occupational health surveillance, health screening, voluntary participation in research or medico-legal procedures.

Regulation 2 is an interpretation provision. Amongst other definitions, there is a definition of adequate training, a concept which is defined with reference to the matters set out in Schedule 2 to the Regulations, and a definition of employer which goes beyond the term as conventionally understood and includes the self-employed, partners in a partnership and contractual relationships.

Regulation 3 sets out the medical exposures to which the Regulations apply.

Regulation 4 requires the employer to provide a framework of procedures for medical exposures. A sole practitioner is required to establish and follow his own procedures. The employer's procedures must cover the matters set out in Schedule 1 as a minimum. Regulation 4 also requires the employer to establish written protocols for standard radiological practices, recommendations concerning referral criteria, quality assurance programmes for standard operating procedures, diagnostic reference levels, and dose constraints and to carry out investigations of incidents and appropriate reviews. Other regulations require the employer to take steps to ensure that a clinical evaluation is recorded of each medical exposure (regulation 7); to ensure that clinical audit is carried out (regulation 8) and that a medical physics expert is involved in every medical exposure as appropriate (regulation 9); to keep an inventory of equipment and to ensure that equipment is limited to a necessary amount (regulation 10).

Regulation 5 sets out the respective responsibilities of practitioners, operators and referrers and makes clear that where the employer also acts in one or more of these roles concurrently he is responsible accordingly. Practitioners and operators are required to follow the framework of procedures provided by the employer and to be adequately trained. The practitioner is responsible for the justification of a medical exposure and for authorisation save where this is carried out by the operator. The operator is responsible for each practical aspect he carries out as well as any authorisation given by him. The referrer must provide medical data as required by the practitioner.

Regulation 6 prohibits any medical exposure from being carried out which has not been justified and authorised and sets out matters to be taken into account for justification.

Regulation 7 provides for the optimisation process, which involves ensuring that doses arising from exposures are kept as low as reasonably practicable. The practitioner and the operator are responsible for elements of the optimisation of medical exposures as specified in regulation 7. Regulations 6 and 7 provide that special attention be given to exposures in medico-legal procedures, health screening or voluntary participation in research, where no direct medical benefit is expected from the exposure or where exposure involves high doses, pregnant or potentially pregnant or breastfeeding females and children. Regulation 7 also provides that certain information and instructions be given where radioactive medicinal products are administered.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Regulation 8 provides for clinical audit to be carried out and regulation 9 for medical physics experts to be consulted where appropriate. Regulation 10 requires the employer to maintain an inventory of equipment and to ensure that the amount of equipment is limited to what is necessary.

Regulation 11 prohibits a practitioner or operator from carrying out a medical exposure without having been adequately trained and requires the employer to keep a record of training qualifications of all practitioners and operators engaged by him. In addition, the employer is under an obligation to take steps to ensure compliance with the training requirements including continuing education after qualification (regulation 4). Again, sole practitioners and partners must keep records about their own training and comply with the requirements themselves. Proof of adequate training is provided by way of a certificate or other evidence attesting to a person's training.

Regulation 12 provides that the Regulations are made enforceable as health and safety regulations under the Health and Safety at Work etc. Act 1974, except that the enforcing authority is the Secretary of State in England, the National Assembly in Wales and the Scottish Ministers in Scotland. Regulation 13 provides that it is a defence to proceedings for an offence under the Regulations that all reasonable steps were taken and due diligence exercised.

Regulation 14 revokes the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 (S.I. [1988/778](#)).