## EXPLANATORY NOTE

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

These Regulations implement, as respects Great Britain, some of the provisions of Council Directive 2013/59/Euratom (OJ No L13,17.1.2014, p1) laying down basic safety standards for protection against the dangers from exposure to ionising radiation. The Directive repeals Directives 89/618/Euratom, 90/641/Euratom, 96/26/Euratom, 97/43/Euratom and 20013/122/Euratom.

In particular, these Regulations transpose Directive requirements relating to dangers arising from ionising radiation in relation to medical exposure. They impose duties on employers and those with responsibilities for administering ionising radiation to protect persons undergoing medical exposures whether as part of their own medical diagnosis or treatment, as part of research, as asymptomatic individuals, as those undergoing non-medical imaging using medical radiological equipment or as carers and comforters of persons undergoing medical exposures.

These Regulations revoke other Regulations relating to medical exposures and prior-authorisation for the administration of radioactive substances for the purposes of diagnosis, treatment and research.

Regulation 2 is an interpretation provision. Regulation 3 sets out the medical exposures to which the Regulations apply.

Regulation 4 sets out conditions under which the Licensing Authority may issue a licence for the administration of radioactive substances. Further provisions relating to the application for and the issuing of such licences are contained in Schedule 1.

Regulation 5 requires the employer and the practitioner who wish to administer radioactive substances to hold a valid licence issued by the Licensing Authority. Such licences will specify the radiological installation and purposes as appropriate.

Regulation 6 requires the employer to establish a framework of general procedures, protocols and quality assurance programmes. The procedures must cover the matters set out in Schedule 2 as a minimum. Written protocols, where appropriate, must be in place for standard radiological practices. The employer must establish recommendations regarding referral guidelines, establish quality assurance programmes for standard operating procedures, review and make available diagnostic reference levels, establish dose constraints where appropriate and raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding.

Regulation 7 requires the employer's procedures to include provision for clinical audit to be carried out.

Regulation 8 sets out the duties of the employer in relation to accidental or unintended medical exposures including provisions for providing information about clinically significant exposures, quality assurance programmes for radiotherapy, analysis and recording of events involving or potentially involving accidental or unintended exposures and processes for investigating and notifying the relevant enforcing authority when significant events have occurred.

Regulation 9 sets out the duties of the enforcing authority with regard to timely dissemination of information relating to significant accidental or unintended exposures.

Regulation 10 sets out the respective responsibilities of practitioners, operators and referrers. Practitioners and operators are required to follow the framework of procedures provided by the employer. The practitioner is responsible for the justification of a medical exposure. Authorisation of exposures is addressed here and in regulation 11. The operator is responsible for each practical

aspect he or she carries out. The referrer must provide medical data as required by the practitioner in order that appropriate justification can take place.

Regulation 11 prohibits any medical exposure which has not been justified and authorised and sets out matters to be taken into account for justification. These include requirements relating to licensing and approval by an expert advisory committee, in the case of research, for exposures involving administration of radioactive substances. Justification of the exposure of carers and comforters is also required and recommendations or guidelines should be considered as part of justification of the exposure of asymptomatic individuals.

Regulation 12 provides for the optimisation process, and specifies the elements that are the responsibilities of the operator and the practitioner, depending on their involvement. Specific requirements are included for exposures in research, for carers and comforters and for exposures involving radioactive substances. Particular regard should be given to the exposures of children, exposures involving high doses, exposures of individuals involved in health screening programmes and pregnant or potentially pregnant or breastfeeding individuals. Regulation 12 also requires the employer to take steps to ensure that a clinical evaluation is recorded of each medical exposure.

Regulation 13 requires employers to provide when requested, to the Secretary of State data relating to dose estimates from diagnostic and interventional medical exposures.

Regulation 14 provides for suitable medical physics experts to be appointed and involved in relation to medical exposures.

Regulation 15 sets out general duties of the employer with respect to medical radiological equipment. These include requirements for quality assurance programmes, appropriate testing of equipment, performance criteria and actions to be taken when equipment does not perform appropriately.

Regulation 16 sets out additional requirements for equipment installed when the Regulations come into force including the transfer of information relating to patient dose where appropriate.

Regulation 17 prohibits a practitioner or operator from carrying out a medical exposure without having been adequately trained, except if supervised appropriately for practical aspects when undergoing training. The employer must keep and make available training records during inspections undertaken by the relevant enforcing authority. Further information regarding adequate training is set out in Schedule 3.

Regulation 18 provides that the Regulations are made enforceable as health and safety regulations under the Health and Safety at Work etc. Act 1974 (c. 37).

Regulation 19 provides there is a defence of due diligence to proceedings for an offence under the Regulations that all reasonable steps were taken and due diligence exercised.

Regulation 20 revokes the Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000/1059) and, subject to transitional provisions relating to existing certificates, the Medicines (Administration of Radioactive Substances) Regulations 1978 (S.I. 1978/1006) and the Medicines (Radioactive Substances) Order 1978 (S.I. 1978/1004).

Regulation 21 and Schedule 4 make provision consequential on the coming into force of these Regulations.

Regulation 22 makes provision for the review of these Regulations at the end of the period of 5 years beginning with the date on which they coming into force.

A full impact assessment has not been prepared to accompany this instrument as it has a low cost to business. However, a regulatory triage assessment accompanies this instrument.