
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Administration of Radioactive Substances) Regulations 1978 (“the principal Regulations”) which restrict the administration of radioactive medicinal products and implement a system of prior authorisation for administration of radioactive substances under Directive 76/579/Euratom(1) (that Directive is no longer in force; the relevant provisions are now in Directive 96/29/Euratom(2)).

Regulation 2 of the principal Regulations prohibits administration of radioactive medicinal products except by a doctor or dentist who holds the relevant certificate issued by the Ministers (“the certificate holder”) or by a person acting in accordance with his directions and makes other provisions relating to administration. Regulations 2 and 3 of these Regulations amend the principal Regulations in order to provide that radioactive medicinal products may be administered by a person who is not a certificate holder in the absence of such directions, in specified circumstances, where the administration involves a medical exposure under the Ionising Radiation (Medical Exposure) Regulations 2000 (“the IRME Regulations”). In particular, regulation 3 substitutes a new regulation 2 of the principal Regulations, so as to make provision for persons who are operators under the IRME Regulations to administer radioactive medicinal products. The operator must be acting in accordance with the relevant procedures and protocols under the IRME Regulations. In addition, he must be acting under the authorisation of, or in accordance with guidelines issued by, a person who is a practitioner under those Regulations and also a certificate holder.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies of the assessment have been placed in the libraries of both Houses of Parliament.

(1) OJNo. L187, 12.7.1976, p1.
(2) OJ No. L159, 29.6.1996, p1.