STATUTORY INSTRUMENTS

2006 No. 2806

The Medicines (Administration of Radioactive Substances) Amendment Regulations 2006

Substitution of regulation 2 of the principal Regulations

3. For regulation 2 of the principal Regulations (control of administration) substitute the following regulation—

"Control of administration

2.—(1) No person shall administer to a human being (otherwise than to himself) any radioactive medicinal product unless he is a doctor or a dentist holding a certificate issued by the Ministers for the purposes of section 60 of the Act in respect of radioactive medicinal products (hereinafter referred to as a "certificate") or a person acting in accordance with the directions of such a doctor or dentist.

(2) Paragraph (1) does not apply where the administration of a radioactive medicinal product would result in a medical exposure and the conditions specified in paragraph (3) are satisfied.

- (3) The conditions referred to in paragraph (2) are that—
 - (a) the medicinal product is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000 which apply to the exposure referred to in paragraph (1);
 - (b) that medical exposure has been authorised by a practitioner or, where it is not practicable for a practitioner to authorise the exposure, an operator acting in accordance with written guidelines issued by a practitioner;
 - (c) the practitioner is the holder of a certificate; and
 - (d) the medicinal product is not a controlled drug.

(4) Where a certificate is issued to a doctor or dentist specifying particular descriptions or classes of radioactive medicinal products—

- (a) the doctor or dentist holding the certificate;
- (b) any person acting in accordance with his directions; and
- (c) an operator acting pursuant to his authorisation of a medical exposure or in accordance with his guidelines,

shall not administer any radioactive medicinal product unless it is a radioactive medicinal product of a description or falling within a class specified in the certificate.

(5) Where, in relation to a radioactive medicinal product specified in a certificate, the purpose for which the administration is also specified—

- (a) the doctor or dentist holding the certificate;
- (b) any person acting in accordance with his directions; and

(c) an operator acting pursuant to his authorisation of a medical exposure or in accordance with his guidelines,

shall not administer any radioactive medicinal product unless it is a radioactive medicinal product of a description or falling within a class specified in the certificate.

(6) Where a certificate issued to a doctor or dentist specifies both the persons to whom any descriptions or classes of radioactive medicinal product may be administered, and the descriptions or classes of radioactive medicinal product which may be administered—

- (a) the doctor or dentist;
- (b) any person acting in accordance with his directions; and
- (c) an operator acting pursuant to his authorisation of a medical exposure, or in accordance with his guidelines,

shall not under that certificate administer any such description or classes of radioactive medicinal product except for the purpose of diagnosis or treatment of a person specified in that certificate."