STATUTORY INSTRUMENTS

2018 No. 121

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018

Made - - - - 31st January 2018

Laid before Parliament 2nd February 2018

Coming into force in accordance with regulation 1(2)

The Secretary of State, being the Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to safety measures in regard to radioactive substances and the emission of ionising radiation, in exercise of the powers conferred by that section makes the following Regulations.

Citation and commencement

1.—(1) These Regulations may be cited as the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018.

(2) These Regulations come into force immediately after the coming into force of the Ionising Radiation (Medical Exposure) Regulations 2017(**3**).

Amendment of the Ionising Radiation (Medical Exposure) Regulations 2017

2.—(1) The Ionising Radiation (Medical Exposure) Regulations 2017(**4**) are amended as follows.

(2) In regulation 3 (application)—

(a) re-number the existing provision as (1);

(b) after the newly re-numbered paragraph (1), insert—

"(2) Regulation 21 and paragraphs 1 and 2 of Schedule 4 apply to the exposure of ionising radiation in Northern Ireland.".

(**1**) S.I. 1977/1718; there are no relevant amendments.

(**2**) 1972 c. 68; section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51), and by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7). In so far as these Regulations deal with matters that are within the devolved competence of Scottish Ministers, the power of the Secretary of State to make regulations in relation to those matters in or as regards Scotland is preserved by section 57(1) of the Scotland Act 1998 (c. 46).

(**3**) S.I. 2017/1322. The 2017 Regulations come into force on 6th February 2018.

(**4**) S.I. 2017/1322.

(3) In regulation 14 (expert advice), in paragraph (2), in sub-paragraph (c) for "sub-paragraphs (b) and (c)" substitute "sub-paragraphs (a) and (b)".

(4) In Schedule 4 (consequential amendments)—

(a) in paragraph 1 (amendment of the Justification of Practices Involving Ionising Radiation Regulations 2004(**5**)), for sub-paragraph (2) substitute—

"(2) For regulation 21 (saving for medical practices) substitute—

"**21.** Nothing in regulation 4(5) or 5(3) shall prevent anything permitted under regulation 11 of the Ionising Radiation (Medical Exposure) Regulations 2017 or regulation 11 of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018(**6**).".";

(b) in paragraph 2 (amendment of the Human Medicines Regulations 2012(**7**))—

(i) for sub-paragraph (2), substitute—

"(2) In regulation 173 (exemption for certain radiopharmaceuticals), for paragraph (d) substitute—

"(d) for administration—

(i) in England and Wales and Scotland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;

(ii) in Northern Ireland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.".";"

(ii) for sub-paragraph (3) (radioactive medicinal products), substitute—

"(3) For regulation 240 (radioactive medicinal products), substitute—

"**Radioactive medicinal products**

240.—(1) Regulation 214(2) does not apply to—

(a) a radioactive substance, administration of which results in a medical exposure; or

(b) any other prescription only medicine if it is being administered in connection with a medical exposure,

if Conditions A to E are met.

(2) Condition A is that the prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to—

(a) in England and Wales and Scotland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations 2017 which apply to the exposure;

(b) in Northern Ireland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 which apply to the exposure.

(3) Condition B is that the medical exposure has been authorised by—

(a) an IRME practitioner; or

(**5**) S.I. 2004/1769.
(**6**) S.R. 2018 No. 17.
(**7**) S.I. 2012/1916.