This Statutory Instrument has been printed to correct errors in S.I. 2017/1322 and is being issued free of charge to all known recipients of that Statutory Instrument.

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—

(**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.

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

(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.

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

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

(a) an IRME practitioner; or

(b) where it is not practical for an IRME practitioner to authorise the exposure, an operator acting in accordance with written guidelines issued by an IRME practitioner.

(4) Condition C is that—

(a) in England and Wales and Scotland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.

(5) Condition D is that the prescription only medicine is not a product subject to special medical prescription.

(6) Condition E is that, in the case of a prescription only medicine that is not a radioactive substance, it is specified in the protocols referred to in paragraph (2).

(7) In this regulation—

"IRME practitioner" means—

(a) in relation to a medical exposure in England and Wales and Scotland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in relation to a medical exposure in Northern Ireland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;

"medical exposure" has the same meaning—

(a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;

"radioactive substance" has the same meaning—

(a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.".".

Signed by authority of the Secretary of State for Health and Social Care.

Stephen Brine
Parliamentary Under-Secretary of State,
Department of Health and Social Care

31st January 2018

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Ionising Radiation (Medical Exposure) Regulations 2017 (S.I. 2017/1322) ("the 2017 Regulations"). In order to give full effect to the policy intention and to correct errors in the 2017 Regulations, these Regulations come into force immediately after the coming into force of the 2017 Regulations.

Regulation 2 amends the 2017 Regulations by:

— inserting appropriate references to territorial extent and application

— correcting an erroneous cross-reference

— amending the Justification of Practices Involving Ionising Radiation Regulations 2004 (S.I. 2004/1769) to provide that the restriction of practices resulting in exposure to ionising radiation in certain cases does not prevent anything done under regulation 11 of the 2017 Regulations or regulation 11 of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 (which deal with justifications for individual exposures to such radiation)

— amending the Human Medicines Regulations 2012 (S.I. 2012/1916)—

- so that the requirement for an authorisation under regulation 46 of those Regulations does not apply where a radiopharmaceutical is prepared in accordance with a licence issued under the 2017 Regulations or the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018
- to disapply, where specified conditions are met, the prohibition in section 214(2) of those Regulations on a person parenterally administering (save in specified circumstances) a prescription only medicine.

A full impact assessment has not been prepared for this instrument as it has a low cost to business.