STATUTORY INSTRUMENTS

2018 No. 430

HEALTH AND SAFETY ENVIRONMENTAL PROTECTION

The Justification of Practices Involving Ionising Radiation (Amendment) Regulations 2018

Made - - - -	*21st March 2018*
Laid before Parliament	*28th March 2018*
Coming into force - -	*18th April 2018*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**).

The Secretary of State is designated(**2**) for the purposes of that section of that Act in relation to basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation.

Citation and commencement

1. These Regulations may be cited as the Justification of Practices Involving Ionising Radiation (Amendment) Regulations 2018 and come into force on 18th April 2018.

Amendment of the Justification of Practices Involving Ionising Radiation Regulations 2004

2. The Justification of Practices Involving Ionising Radiation Regulations 2004(**3**) are amended in accordance with regulations 3 to 24.

Amendment of regulation 2 (application)

3.—(1) Regulation 2 is amended as follows.

(2) For "1996" substitute "2013".

(**1**) 1972 c. 68. Section 2(2) was amended by section 27(1)(a) of the Legislative 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).

(**2**) S.I. 1991/2289.

(**3**) S.I. 2004/1769.

Amendment of regulation 3 (interpretation)

4.—(1) Regulation 3 is amended as follows.

(2) For paragraph (1) substitute—

"(1) In these Regulations, "the 2013 Directive" means Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom(**4**)."

(3) In paragraph (2)—

(a) for "1996" substitute "2013";

(b) for "Article 1" substitute "Article 4".

(4) In paragraph (3), in the table—

(a) omit the entry relating to "devolved competence";

(b) after the entry relating to "found to be justified" insert—

"imaging practice	regulation 21A(2)";

(c) in the entry relating to "new class or type of practice", for "regulation 4(1)" substitute "regulations 4(1) and 20B";

(d) after the entry relating to "Wales" insert—

"Welsh Ministers	regulation 6(4)(h)".

Amendment of regulation 4 (justification of new classes and types of practice)

5.—(1) Regulation 4 is amended as follows.

(2) For paragraph (1) substitute—

"(1) Subject to regulation 20B, a class or type of practice is "new" for the purposes of these Regulations if—

(a) no practice in that class or type was carried out in the United Kingdom before 6th February 2018; or

(b) a practice in that class or type was carried out in the United Kingdom before 6th February 2018 but in breach of a requirement not to carry out a practice in that class or type until that class or type had been found to be justified,

and in either case the class or type of practice has not been found to be justified."

(3) For paragraph (2) substitute—

"(2) In these Regulations, "justified" in relation to a class or type of practice means that the individual or societal benefit resulting from the class or type of practice outweighs the health detriment that it may cause."

(4) In paragraph (3)(b) for "or 7" substitute ", 7 or 21C(4)".

(5) After paragraph (3) insert—

"(3A) In making a justification decision in respect of a class or type of practice involving occupational and public exposures, the Justifying Authority must take into account both categories of exposure.

(**4**) OJ L 13, 17.1.2014, p.1.

(3B) In making a justification decision in respect of a class or type of practice involving medical exposure, the Justifying Authority must take into account medical and, where relevant, occupational and public exposures."

Amendment of regulation 5 (existing and prohibited practices)

6.—(1) Regulation 5 is amended as follows.

(2) In paragraph (1)(a) for "13th May 2000" substitute "6th February 2018 without breaching any requirement not to carry out a practice in that class or type until that class or type had been found to be justified".

Amendment of regulation 6 (justifying authority)

7.—(1) Regulation 6 is amended as follows.

(2) In paragraph (1)(d) for "National Assembly for Wales" substitute "Welsh Ministers".

(3) After paragraph (1) insert—

"(1A) A person must not exercise functions under these Regulations in relation to a practice, except those listed in paragraph (1B), unless that person is functionally separate from all other persons concerned with the promotion or utilisation of that practice.

(1B) The functions referred to in paragraph (1A) are those of—

(a) receiving applications under regulation 13(1);

(b) maintaining the register under regulation 19(1);

(c) making the register available to the public under regulation 19(3);

(d) carrying out reviews and publishing reports under regulation 28."

(4) In paragraph (2)—

(a) in the words before sub-paragraph (a)—

(i) at the beginning, for "The" substitute "In addition to the limitation in paragraph (1A), the";

(ii) after "shall be" insert "further";

(b) in sub-paragraph (b), after devolved competence, insert ", within the meaning of section 54 of the Scotland Act 1998(**5**)";

(c) in sub-paragraph (d)—

(i) for "National Assembly for Wales" substitute "Welsh Ministers";

(ii) for "functions under these Regulations" to the end substitute "justifying the class or type of practice involved falls within devolved competence, within the meaning of section 58A of the Government of Wales Act 2006(**6**)".

(5) In paragraph (3)(a) for "National Assembly for Wales" substitute "Welsh Ministers".

(6) In paragraph (4)—

(a) omit sub-paragraph (a);

(b) in sub-paragraph (g) for "section 155 of the Government of Wales Act 1998" substitute "section 158 of the Government of Wales Act 2006";

(c) after sub-paragraph (g) insert—

(**5**) 1998 c. 46, to which there are amendments not relevant to these Regulations.
(**6**) 2006 c. 32. Section 58A is inserted by section 19(1) of the Wales Act 2017 (c. 4). Section 19(1) is commenced by regulation 3 of the Wales Act 2017 (Commencement No. 4) Regulations 2017 (S.I. 2017/1179) and comes into force on 1st April 2018.

";

(h) "the Welsh Ministers" has the meaning prescribed by section 45 of the Government of Wales Act 2006".

Amendment of regulation 7 (transitional arrangements – new classes or types of practice)

8.—(1) Regulation 7 is amended as follows.

(2) In paragraph (a)—

(a) for "the date of the coming into force of these Regulations" substitute "18th April 2018";

(b) for "before the coming into force of these Regulations" substitute "before 18th April 2018".

Amendment of regulation 10 (review of existing practices)

9.—(1) Regulation 10 is amended as follows.

(2) In paragraph (2)—

(a) for "may", in the first place it occurs, substitute "must";

(b) for "it" substitute "carrying out a review";

(c) after "and may" insert ", having carried out a review,".

(3) After paragraph (3) insert—

"(3A) The Justifying Authority must consider carrying out a review of an existing class or type of practice if the Justifying Authority becomes aware that the condition set out in paragraph (4)(a) is satisfied."

(4) In paragraph (4)—

(a) in the words before sub-paragraph (a) for "and (3)" substitute ", (3) and (3A)";

(b) for sub-paragraph (a) substitute—

"(a) new and important evidence is acquired about the efficacy or potential consequences of—

(i) the class or type of practice; or

(ii) other techniques or technologies that have the same objective as it; or".

Amendment of regulation 13 (application procedure)

10.—(1) Regulation 13 is amended as follows.

(2) In paragraph (1)—

(a) for "or 10" substitute ", 10, 21C or 21E";

(b) for "National Assembly for Wales" substitute "Welsh Ministers".

(3) In paragraph (3) for "or 10" substitute ", 10, 21C or 21E".

Amendment of regulation 15 (time for determining applications)

11.—(1) Regulation 15 is amended as follows.

(2) In paragraph (1) for "or 12" substitute ", 12, 21C or 21E".

Amendment of regulation 18 (consultation)

12.—(1) Regulation 18 is amended as follows.

(2) In paragraph (1) for ", a determination under regulation 12" substitute "or a determination under regulation 12 or 21C".

(3) In paragraph (2) after "16, 17," insert "21C,".

Amendment of regulation 19 (register)

13.—(1) Regulation 19 is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a) for "or 12" substitute "12 or 21C";

(b) in sub-paragraph (b) after "Part 3" insert "or regulation 21C";

(c) after sub-paragraph (b) insert—

"(ba) approvals granted under regulation 21E;".

(3) In paragraph (2)—

(a) for "National Assembly for Wales" substitute "Welsh Ministers";

(b) after "9, 10 or 11" insert "or a determination under regulation 21C,".

Amendment of regulation 20 (addition of radioactive substances to personal ornaments, toys or cosmetics)

14.—(1) Regulation 20 is amended as follows.

(2) For the heading of regulation 20 substitute "Radioactive substances in personal ornaments, toys and cosmetics".

(3) In regulation 20, after paragraph (1) insert—

14.—"(1A) A person must not—

(a) carry out a practice involving the activation of materials used in toys or personal ornaments;

(b) knowingly or recklessly import or export toys or personal ornaments in which materials have been activated;

(c) knowingly or recklessly import or export materials that have been activated for use in toys or personal ornaments,

where that activation results, at the time of the placing on the market of the products or at the time of their manufacture, in an increase in activity which cannot be disregarded from a radiation protection point of view."

New Part 6A (practices involving consumer products)

15. After regulation 20 insert—