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(**a**).

The Secretary of State is designated(**b**) 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(**c**) 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".

Amendment of regulation 3 (interpretation)

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

(**a**) 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).

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

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

(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(**a**)."

(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.

(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.

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

(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(**a**)";

(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(**b**)".

(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—

";

(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";

(**a**) 1998 c. 46, to which there are amendments not relevant to these Regulations.

(**b**) 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.

(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—

"(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—

"Part 6A

Practices involving consumer products

Justification of classes or types of practice involving consumer products

20A.—(1) Any person intending to manufacture or import a consumer product for which the intended use is likely to belong to a new class or type of practice must, prior to commencing manufacture or import, make an application to the Justifying Authority under regulation 9 in respect of the intended use of the consumer product and provide to the Justifying Authority the information listed in paragraph 1 of Schedule A1.

(2) In making a justification decision in respect of a new class or type of practice involving the use of a consumer product, the Justifying Authority must take into account the information provided under paragraph (1) and must assess the factors listed in paragraph 2 of Schedule A1.

(3) A person must not sell or make available to the public a consumer product where—

(a) its intended use would constitute a contravention of regulation 4(5) or 5(3); or

(b) its intended use would constitute a practice and that practice would not satisfy the criteria described in any of the categories listed in paragraph 1 of Schedule 1 to the Ionising Radiations Regulations 2017(**a**).

(**a**) S.I. 2017/1075.

Classes or types of practice involving the activations of material in consumer products

20B. A class or type of practice involving activation of material resulting in an increase in activity in a consumer product, which at the time of placing that consumer product on the market cannot be disregarded from a radiation protection point of view, is "new" for the purposes of these Regulations if that class or type of practice has not been found to be justified."

Amendment of regulation 21 (saving for medical practices)

16.—(1) Regulation 21 is amended as follows.

(2) For "anything" to the end substitute—

"any exposure—

(a) described in paragraphs (a) to (e) of regulation 3 of the Ionising Radiation (Medical Exposure) Regulations 2017(**a**) and permitted under regulation 11 of those Regulations;

(b) described in paragraphs (a) to (e) of regulation 3 of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018(**b**) and permitted under regulation 11 of those Regulations."

New Part 7A (practices involving non-medical imaging exposure)

17. After regulation 21 insert—

"PART 7A

Practices involving non-medical imaging exposure

Application of this Part

21A.—(1) This Part applies to imaging practices.

(2) In these Regulations, an "imaging practice" is a practice involving non-medical imaging exposure other than one that uses medical radiological equipment.

Identification of practices

21B. The Secretary of State must take reasonable steps to ensure the identification of imaging practices.

Determinations and new and existing practices

21C.—(1) The Justifying Authority may, and on the application of any other person must, determine whether a particular imaging practice belongs to a new or existing class or type of practice.

(2) A person must not carry out a particular imaging practice that is new unless paragraph (5) applies.

(3) A particular imaging practice is "new" for the purpose of this regulation if—

(a) it was not carried out in the United Kingdom before 6th February 2018; or

(**a**) S.I. 2017/1322.
(**b**) S.R. 2018 No. 17

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

and in either case the Justifying Authority has not made a positive determination in respect of that particular imaging practice.

(4) A determination made by the Justifying Authority under paragraph (1) is "positive" in relation to a particular imaging practice unless—

(a) the Justifying Authority determines that the particular imaging practice belongs to a new class or type of practice;

(b) the Justifying Authority determines that the particular imaging practice belongs to an existing class or type of practice and it has been determined in the most recent justification decision applicable to that class or type of practice that it is not justified;

(c) the determination is not the most recent determination made under paragraph (1) that is applicable to that particular imaging practice;

(d) the determination does not apply to the part of the United Kingdom in which it is proposed that that particular imaging practice be carried out.

(5) Subject to regulation 5(3)—

(a) a person may carry out a particular imaging practice that is new for a period of six months beginning on 18th April 2018, if that person first carried out the particular imaging practice before 18th April 2018;

(b) that person may continue to carry out that imaging practice after the expiry of that period—

(i) if that person has, within that period, applied for a determination under paragraph (1); and

(ii) until that determination has been made.

Individual justification and regular review

21D.—(1) A person carrying out an imaging practice must—

(a) ensure that each individual exposure is justified; or

(b) carry out regular reviews of the implementation of that imaging practice and after each review promptly provide to the Justifying Authority a written report summarising the results of that review.

(2) For the purposes of this regulation an individual exposure is justified where the individual or societal benefit resulting from the exposure outweighs the health detriment that it may cause.

(3) Reviews under paragraph (1)(b) must be carried out at a frequency which is appropriate having regard to the specific circumstances of the imaging practice including, but not limited to, how often the exposures take place.

Approvals and requirements for practices

21E.—(1) A person must not carry out a particular imaging practice unless the Justifying Authority has granted an approval to that person in respect of that particular imaging practice (an "Approval") and the Justifying Authority has not withdrawn the Approval.

(2) A person may apply to the Justifying Authority for an Approval in respect of a particular imaging practice.

(3) The Justifying Authority must in any Approval it grants set out requirements, including criteria for implementation, with which the person must comply in carrying out the particular imaging practice.

(4) In establishing the requirements to be contained in an Approval, the Justifying Authority must consult—

(a) the other persons listed in regulation 6(1); and

(b) any of the persons listed in regulation 18(1)(a) whom the Justifying Authority considers it appropriate to consult.

(5) The Justifying Authority may serve a notice on a person if the Justifying Authority is of the opinion that the person is not complying with the requirements contained in that person's Approval in carrying out the particular imaging practice to which the Approval relates (a "warning notice").

(6) The warning notice must specify—

(a) the matters constituting the failure to comply with the requirements in the Approval;

(b) the steps that must be taken to remedy the failure to comply; and

(c) the period within which those steps must be taken, which must be no less than 28 days unless in the opinion of the Justifying Authority it is necessary for those steps to be taken more quickly.

(7) The Justifying Authority may by notice withdraw an Approval from a person if—

(a) the Justifying Authority has served a warning notice on that person;

(b) the period specified in the warning notice for taking the steps to remedy the failure has passed; and

(c) the Justifying Authority is of the opinion that the person has not taken the steps specified in the warning notice to remedy the failure to comply.

(8) Where the Justifying Authority has withdrawn an Approval from a person under paragraph (7), the Justifying Authority may subsequently grant a new Approval to that person in respect of the same or any other particular imaging practice.

(9) The Justifying Authority may alter the requirements in an Approval if—

(a) the Justifying Authority has consulted the person who holds the Approval;

(b) the Justifying Authority has served a notice on the person who holds the Approval (an "alteration notice"); and

(c) the alteration notice contains—

(i) the new requirements for the particular imaging practice; and

(ii) the date, which must be later than the date of the alteration notice, from which those new requirements are to apply.

Dose constraints

21F. The dose constraints for imaging practices must be significantly below the dose limits set out in paragraphs 5 and 7 of Schedule 3 to the Ionising Radiations Regulations 2017.

Consent

21G.—(1) A person proposing to subject an individual to an exposure as part of an imaging practice must first provide a reasonable level of information about the proposed exposure to, and obtain prior consent for the exposure from, the individual to be exposed.

(2) The requirement in paragraph (1) to obtain prior consent does not apply to law enforcement authorities.

(3) In this regulation, "law enforcement authority" means any authority responsible for preventing, detecting, investigating, combating and punishing criminal offences, including, but not limited to, the police, any prosecutor, any judicial authority and any prison authority.

(4) In paragraph (3), "prison authority" includes—

(a) a governor of a prison;

(b) an officer of a prison;

(c) a person working at a prison who is authorised by the governor of the prison to exercise powers of search;

(d) a director of a contracted out prison;

(e) a prisoner custody officer of a contracted out prison;

(f) a worker at a contracted out prison who is authorised by the director of the contracted out prison to carry out restricted activities.

(5) Expressions used in paragraph (4)(d) to (f) have the meanings given in Part IV of the Criminal Justice Act 1991(**a**)."

Amendment of regulation 22 (contravention notices)

18.—(1) Regulation 22 is amended as follows.

(2) In paragraph (1)—

(a) for "regulation 23" substitute "regulations 23 and 23A";

(b) for "or 20" substitute ", 20, 20A(1), 20A(3), 21C(2), 21D(1), 21E(1), 21F or 21G(1)".

New regulation 23A (inspections)

19. After regulation 23 insert—

"Inspections

23A.—(1) The Justifying Authority must, for the purpose of monitoring whether a person has committed a relevant breach or has failed to comply with any of the requirements in an approval granted under regulation 21E, establish an inspection programme taking into account—

(a) the potential magnitude and nature of the hazard associated with practices;

(b) a general assessment of radiation protection issues in the practices;

(c) the state of compliance with these Regulations.

(2) The Justifying Authority must ensure that the findings from each inspection carried out under the inspection programme are recorded and communicated to the person concerned. If findings are related to an outside worker or workers, where appropriate, the Justifying Authority must also ensure that the findings are communicated to the employer."

New regulation 25A (application of criminal offences to the Crown)

20. After regulation 25 insert—

"Application of criminal offences to the Crown

25A.—(1) No contravention by the Crown of any provision of these Regulations makes the Crown criminally liable.

(2) Paragraph (1) does not affect the criminal liability of persons in the service of the Crown.

(**a**) 1991 c. 53. Section 84 was substituted by section 96 of the Criminal Justice and Public Order Act 1994 (c. 33). Section 85 was amended by section 18 of the Offender Management Act 2007 (c. 21); section 85 also contains other amendments which are not relevant to these Regulations. Section 86B was inserted by section 18(2) of the Offender Management Act 2007. Section 89 was amended by section 101(4) of the Criminal Justice and Public Order Act 1994.

(3) The High Court or, in Scotland, the Court of Session may, on the application of a person appearing to the court to have an interest, declare unlawful any act or omission of the Crown which would, but for paragraph (1), constitute an offence under these Regulations."

Amendment of regulation 27 (delegation of enforcement powers)

21.—(1) Regulation 27 is amended as follows.

(2) In paragraph (1)—

(a) after "following powers" insert "and functions";

(b) after sub-paragraph (b) insert—

"(ba) the inspection functions under regulation 23A;".

New Part 9 (miscellaneous)

22. After regulation 27 insert—

"PART 9

Miscellaneous

Review

28.—(1) The Secretary of State must from time to time—

(a) carry out a review of the regulatory provision contained in these Regulations, and

(b) publish a report setting out the conclusions of the review.

(2) The first report must be published before 18th April 2023.

(3) Subsequent reports must be published at intervals not exceeding 5 years.

(4) Section 30(3) of the Small Business, Enterprise and Employment Act 2015(**a**) requires that a review carried out under this regulation must, so far as is reasonable, have regard to how the 2013 Directive is implemented in other member States.

(5) Section 30(4) of the Small Business, Enterprise and Employment Act 2015 requires that a report published under this regulation must, in particular—

(a) set out the objectives intended to be achieved by the regulatory provision referred to in paragraph (1)(a),

(b) assess the extent to which those objectives are achieved,

(c) assess whether those objectives remain appropriate, and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(6) In this regulation, "regulatory provision" has the same meaning as in sections 28 to 32 of the Small Business, Enterprise and Employment Act 2015 (see section 32 of that Act)."

New Schedule A1 (practices involving consumer products)

23. Before Schedule 1 insert—

(**a**) 2015 c. 26; section 30(3) was amended by section 19 of the Enterprise Act 2016 (c. 12)

"SCHEDULE A1 Regulation 20A

Practices involving consumer products

1. The information referred to in paragraph (1) of regulation 20A is—

(a) the intended use of the product;

(b) the technical characteristics of the product;

(c) in the case of products containing radioactive substances, information as to their means of fixation;

(d) dose rates at relevant distances for the use of the product, including dose rates at a distance of 0.1 m from any accessible surface;

(e) expected doses to regular users of the product;

(f) all other relevant information so as to enable the Justifying Authority to make a justification decision in respect of the relevant class or type of practice.

2. The factors referred to in paragraph (2) of regulation 20A are whether—

(a) the performance of the consumer product justifies its intended use;

(b) the design is adequate in order to minimise exposures in normal use and the likelihood and consequences of misuse or accidental exposures, or whether there should be conditions imposed on the technical and physical characteristics of the product;

(c) the product is adequately designed so that its intended use would constitute a practice that would satisfy the criteria described in one of the categories listed in paragraph 1 of Schedule 1 to the Ionising Radiations Regulations 2017 and, where applicable, is of an approved type for the purposes of paragraph 1(d)(i) of Schedule 1 to the Ionising Radiations Regulations 2017 and does not necessitate specific precautions for disposal when no longer in use;

(d) the product is appropriately labelled and suitable documentation is provided to the consumer with instructions for proper use and disposal."

Amendment of Schedule 3 (offences by bodies corporate etc. in Scotland)

24.—(1) Schedule 3 is amended as follows.

(2) For each of the three instances of "this Act" substitute "these Regulations".

Richard Harrington
Parliamentary Under Secretary of State
21st March 2018 Department for Business, Energy and Industrial Strategy

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are part of a package of measures to transpose Council Directive 2013/59/Euratom (OJ No. L13, 17.1.2014) 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. The Regulations extend to the whole of the United Kingdom.

Regulations 3 to 24 contain amendments to the Justification of Practices Involving Ionising Radiation Regulations 2004 (the "2004 Regulations"). In summary:

(a) regulation 5 of these Regulations amends regulation 4 of the 2004 Regulations. It sets out a new definition of when a class or type of practice will be "new", as well as what "justified" means in relation to a class or type of practice. It also sets out new requirements for the making of justification decisions in respect of classes or types of practice involving both occupational and public exposures and in respect of classes or types of practice involving medical exposure;

(b) regulation 7 amends regulation 6 to add a requirement for the Justifying Authority to be functionally separate from all other persons concerned with the promotion or utilisation of practices in relation to which the Justifying Authority is exercising functions;

(c) regulation 9 amends regulation 10 to require the Justifying Authority to consider carrying out a review of an existing class or type of practice where new and important evidence about it is acquired;

(d) regulation 14 amends regulation 20 to prohibit practices involving the activation of materials used in toys or personal ornaments where that may increase their radioactivity. It also prohibits the import and export of such products and materials;

(e) regulation 15 inserts new regulations 20A and 20B, which set out requirements relating to consumer products whose intended use would constitute a practice. They also describe when a class or type of practice involving activation of material in a consumer product is considered to be "new";

(f) regulation 16 amends regulation 21 to preserve an exemption from the requirement for justification at the class- or type-level for medical exposures that are permitted by the Ionising Radiation (Medical Exposure) Regulations 2017, but to exclude from the exemption imaging exposures carried out for non-medical purposes;

(g) regulation 17 inserts new regulations 21A to 21G, which introduce specific requirements for persons carrying out non-medical imaging exposures not using medical radiological equipment (an "imaging practice"). Regulation 21C sets out a procedure for seeking a justification determination in respect of an imaging practice. New imaging practices must be subjected to this procedure before they can be carried out. Regulation 21D requires persons carrying out imaging practices either to ensure that each individual exposure is justified or to carry out regular reviews. Regulation 21E sets out the process for the granting of approvals to persons carrying out imaging practices and the establishing of specific requirements that are contained in those approvals. Regulation 21F sets out requirements for dose constraints for imaging practices. Regulation 21G imposes information and consent requirements on the carrying out of imaging practices;

(h) regulation 19 inserts new regulation 23A, which obliges the Justifying Authority to establish an inspection programme and to ensure that the findings of inspections carried out under the programme are communicated to the persons concerned;

(i) regulation 20 inserts new regulation 25A, which provides that the Crown cannot be criminally liable for a breach of any of the requirements of the 2004 Regulations;

(j) regulation 22 inserts new regulation 28, which requires the Secretary of State to carry out a review of the 2004 Regulations at intervals not exceeding 5 years;

(k) regulation 23 inserts new Schedule A1, which sets out further relevant information that is referenced in regulation 20A of the 2004 Regulations.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£6.00

UK201803271031 04/2018 19585

http://www.legislation.gov.uk/id/uksi/2018/430

ISBN 978-0-11-116802-8