

---

STATUTORY INSTRUMENTS

---

**2004 No. 1769**

**The Justification of Practices Involving  
Ionising Radiation Regulations 2004**

**PART 1**

*Interpretation and General*

**Title and commencement**

1. These Regulations may be cited as the Justification of Practices Involving Ionising Radiation Regulations 2004 and shall come into force on 2nd August 2004.

**Application**

2. These Regulations apply to practices only to the extent to which the 1996 Directive applies to them.

**Interpretation**

3.—(1) “The 1996 Directive” means Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (1).

(2) Expressions and words used in both these Regulations and the 1996 Directive have the same meaning for the purposes of these Regulations as they do in that Directive, whether or not they are defined in Article 1 of that Directive.

(3) The following table shows other provisions defining expressions for the purposes of these Regulations—

---

devolved competence	regulation 6(4)(a)
contravention notice	regulation 22(2)
existing class or type of practice	regulation 5(1)
found to be justified	regulation 4(4)
justification decision	regulations 4(3) and 14(1)
justified	regulation 4(2)
Justifying Authority	regulation 6
new class or type of practice	regulation 4(1)
Northern Ireland	regulation 6(4)(e)

---

(1) OJ L 159, 29.6.1996, p.1.

---

Northern Ireland department	regulation 6(4)(f)
Scotland	regulation 6(4)(d)
Scottish Ministers	regulation 6(4)(b)
transferred matter	regulation 6(4)(c)
Wales	regulation 6(4)(g).

---

## PART 2

### *General Principles*

#### **Justification of new classes or types of practice**

4.—(1) A class or type of practice is “new” for the purposes of these Regulations if no practice in that class or type was carried out in the United Kingdom before 13th May 2000, and neither has the class or type of practice been found to be justified.

(2) In these Regulations, “justified” in relation a class or type of practice means justified by its economic, social or other benefits in relation to the health detriment it may cause.

(3) A “justification decision” for the purposes of these Regulations is a decision which—

- (a) is made by the Justifying Authority in the form specified in regulation 14, and which determines whether a class or type of practice is justified; and
- (b) in regulation 5(3) or 7, or for the purpose of determining whether a class or type of practice has been justified for the purpose of regulation 4(5), applies to the part of the United Kingdom in which it is proposed that the practice in question be carried out.

(4) A class or type of practice is “found to be justified” for the purposes of these Regulations if a justification decision has been made determining that it is justified.

(5) No person shall carry out a practice, resulting in exposure to ionising radiation, belonging to a new class or type of practice unless regulation 7 (transitional arrangements) applies.

#### **Existing and prohibited practices**

5.—(1) In these Regulations, a class or type of practice involving exposure to ionising radiation is an “existing class or type of practice” if either—

- (a) a practice in that class or type was carried out in the United Kingdom before 13th May 2000; or
- (b) it has been found to be justified; or both.

(2) Subject to paragraph (3), a person may carry out a practice, resulting in exposure to ionising radiation, belonging to an existing class or type of practice.

(3) No person shall carry out a practice, resulting in exposure to ionising radiation if—

- (a) it has been determined in the most recent justification decision applicable to that class or type of practice that the class or type of practice to which it belongs is not justified; and
- (b) the date, specified under regulation 11(2)(a) for ceasing to carry out the practice has passed.

#### **Justifying Authority**

6.—(1) In these Regulations, “the Justifying Authority” means such of the following persons as may exercise a function under these Regulations—

- (a) the Secretary of State;
- (b) the Scottish Ministers;
- (c) a Northern Ireland department;
- (d) the National Assembly for Wales.

(2) The exercise of functions under these Regulations by the Justifying Authority, except those of receiving applications under regulation 13(1) or being consulted under regulation 18(2), shall be limited as provided in regulation 14(2) and as set out below—

- (a) any function may be exercised by the Secretary of State;
- (b) functions may be exercised by the Scottish Ministers only insofar as justifying the class or type of practice involved falls within devolved competence;
- (c) functions may be exercised by a Northern Ireland department only in relation to Northern Ireland and insofar as justifying the class or type of practice involved is a transferred matter;
- (d) functions may be exercised by the National Assembly for Wales only insofar as functions under these Regulations are functions exercisable by the Assembly by virtue of an order made under section 22 of the Government of Wales Act 1998(2).

(3) Where in these Regulations the Justifying Authority is obliged to perform a function, that obligation shall fall as follows—

- (a) on the Scottish Ministers, a Northern Ireland department, or the National Assembly for Wales, insofar as they may perform that function, having regard to paragraph (2) and to regulation 14(2); and otherwise
- (b) on the Secretary of State.

(4) In these Regulations—

- (a) “devolved competence” has the meaning prescribed by section 54 of the Scotland Act 1998(3);
- (b) “the Scottish Ministers” has the meaning prescribed by section 44 of the Scotland Act 1998;
- (c) “transferred matter” has the meaning prescribed by section 4 of the Northern Ireland Act 1998(4);
- (d) “Scotland” has the meaning prescribed by section 126 of the Scotland Act 1998;
- (e) “Northern Ireland” has the meaning prescribed by section 98(1) of the Northern Ireland Act 1998;
- (f) “Northern Ireland department” has the meaning prescribed by section 21 of the Northern Ireland Act 1998;
- (g) “Wales” has the meaning prescribed by section 155 of the Government of Wales Act 1998.

### **Transitional Arrangements- new classes or types of practice**

7. Subject to regulation 5(3)—

- (a) a person may carry out a practice of a new class or type, for a period of six months beginning on the date of the coming into force of these Regulations, if he first carried out the practice in the United Kingdom before the coming into force of these Regulations;
- (b) that person may continue to carry out that practice after the expiry of that period—

---

(2) 1998 c. 38, to which there are amendments not relevant to these Regulations.

(3) 1998 c. 46, to which there are amendments not relevant to these Regulations.

(4) 1998 c. 47, to which there are amendments not relevant to these Regulations.

- (i) if he has, within that period, applied for a justification decision; and
- (ii) until a justification decision has been made.

#### **Transitional Arrangements- earlier justification decisions**

- 8.**—(1) This regulation applies when there has been a determination which—
- (a) expressly determines whether or not a practice, or a class or type of practice is justified;
  - (b) was made prior to the coming into force of these Regulations; and
  - (c) was made by one of the persons listed in regulation 6(1) or by a person acting with the authority of one of those persons.
- (2) A determination to which this regulation applies shall—
- (a) be treated as a justification decision for the purposes of these Regulations;
  - (b) be treated as limited to the same extent that the power of the person making it, or under whose authority it was made, is limited by sub-paragraphs (a) to (d) of regulation 6(2); and
  - (c) if it was limited to a particular practice, be treated as a justification decision whose scope is limited to the same extent as was the determination in question.
- (3) Any determination to which this regulation applies which determined that a practice or a class or type of practice was not justified shall be treated as having specified, for the purpose of regulation 11(2)(a), the date these Regulations come into force unless a later date was specified in the determination.

## **PART 3**

### *Applications and Determinations*

#### **Consideration of new practices**

**9.**—(1) A person may apply to the Justifying Authority for a justification decision in respect of a new class or type of practice.

(2) Having received an application under paragraph (1) the Justifying Authority shall, subject to regulation 14(2), consider it and make a justification decision in respect of that class or type of practice.

(3) The Justifying Authority may, subject to regulation 14(2), without receiving an application under paragraph (1), make a justification decision in respect of a new class or type of practice.

#### **Review of existing practices**

**10.**—(1) A person may apply to the Justifying Authority to review an existing class or type of practice if one of the conditions set out in paragraph (4) is satisfied.

(2) Having received an application under paragraph (1), the Justifying Authority may, subject to regulation 14(2), consider it and may make a new justification decision in respect of that class or type of practice.

(3) The Justifying Authority may, subject to regulation 14(2), without receiving an application under paragraph (1), review an existing class or type of practice if one of the conditions set out in paragraph (4) is satisfied and make a new justification decision in respect of that class or type of practice.

(4) The conditions referred to in paragraphs (1) and (3) above are that—

- (a) new and important evidence about its efficacy or consequences is acquired; or
- (b) there has been a justification decision that it is not justified.

#### **Conditions and consequential matters**

**11.**—(1) A justification decision may be made subject to such conditions as the Justifying Authority may consider appropriate.

(2) If the Justifying Authority in considering a justification decision determines that an existing class or type of practice is not justified he—

- (a) shall specify in the justification decision a date, which may be later than the date of the justification decision, after which persons must cease from carrying out practices of that class or type; and
- (b) may specify by notice served on an operator or any other person, steps which that person is required to take which the Justifying Authority considers appropriate as a consequence of the decision.

#### **Determination whether a practice is new or existing**

**12.**—(1) The Secretary of State may, and at the request of any other person shall, determine whether a practice belongs to a new or existing class or type of practice for the purposes of these Regulations.

(2) Any application under regulation 9 or 10 shall be deemed to include a request under paragraph (1).

## **PART 4**

### *Procedures*

#### **Application procedure**

**13.**—(1) A person may make an application under regulation 9 or 10 to the Secretary of State, the Scottish Ministers, a Northern Ireland department, or the National Assembly for Wales, and those persons may receive such applications, without limitation as to the territorial extent or the subject matter of the application.

(2) The recipient of an application shall forthwith upon receipt forward a copy of it to such of the persons listed in regulation 6(1) as did not receive the application, which copies shall be treated as if they were applications.

(3) Any application under regulation 9 or 10 shall, notwithstanding any statement by the applicant of the geographical extent or limit of his application, be treated as if it were an application made to each of the persons listed in regulation 6(1) insofar as each is able pursuant to regulation 6(2) to exercise the function of determining the application.

#### **Form of applications and decisions**

**14.**—(1) Any justification decision, required or permitted to be made by these Regulations, that—

- (a) determines that a class or type of practice is justified, where it was not previously justified; or
- (b) determines that a class or type of practice is no longer justified; or
- (c) introduces or changes conditions relating to the justification of a class or type of practice,

shall be made by the Justifying Authority in the form of regulations, by exercising such powers as the Justifying Authority has which arise apart from these Regulations, including but not limited to powers under section 2(2) of the European Communities Act 1972(5).

(2) In the event that any of the persons mentioned in regulation 6(1) as constituting the Justifying Authority has no such power as is mentioned in paragraph (1), he shall not make a justification decision.

(3) Any application, determination, decision or notice made or given under these Regulations, other than a justification decision required by paragraph (1) to be in the form of regulations, shall be in writing, unless paragraph (4) applies.

(4) Any person to whom these Regulations require any application, determination, decision, notice or other information to be communicated may agree to receive that application, determination, decision, notice or other information by any electronic means of communication or other information technology, but may not require it to be so communicated.

(5) Without prejudice to paragraph (1), the Justifying Authority shall take such steps as he considers appropriate to bring any determination, decision or notice made or given under these Regulations to the attention of any person likely to be affected by it.

(6) After making any determination or justification decision under these Regulations, the Justifying Authority which has made the determination or decision shall forthwith give notice of the determination or decision and of where a copy of the determination or decision can be obtained, as follows:

- (a) for a determination or decision affecting England, Wales, or both, in the London Gazette;
- (b) for a determination or decision affecting Scotland, in the Edinburgh Gazette;
- (c) for a determination or decision affecting Northern Ireland, in the Belfast Gazette.

#### **Time for determining applications**

15.—(1) The Justifying Authority or, in the case of regulation 12, the Secretary of State shall, within one month of receiving an application or request under regulation 9, 10 or 12, notify the applicant of the period within which it will be determined.

(2) The Justifying Authority or, in the case of regulation 12, the Secretary of State shall, within the period notified to the applicant under paragraph (1) or such further period as shall be notified to the applicant—

- (a) make a justification decision or determination in relation to that application; or
- (b) (if he has decided not to make a justification decision on an application made under regulation 10) notify the applicant of his intention not to make a justification decision in respect of the application.

---

(5) The European Communities (Designation) (No3) Order 1991, [SI 1991/2289](#) designates the Secretary of State and any Northern Ireland department in relation to measures relating to basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation. By virtue of the Scotland Act 1998, Schedule 8, paragraph 1, the Scottish Ministers do not require designation to make regulations under section 2(2) of the European Communities Act 1972. At the time of the making of these Regulations, no orders designating the National Assembly for Wales pursuant to section 29 of the Government of Wales Act 1998 have been made in relation to these functions.

## PART 5

### *Information, Consultation and Publicity*

#### **Information**

**16.**—(1) For the purpose of the discharge of any function under these Regulations, the Justifying Authority may, by notice served on any person, require that person to furnish such information as is specified in the notice, within such period as is so specified.

(2) A notice served pursuant to paragraph (1) may only specify such information as is in the person's possession or which the person may reasonably be expected to furnish.

(3) A notice served pursuant to paragraph (1) may be withdrawn or varied by the Justifying Authority.

(4) The period specified in the notice pursuant to paragraph (1) shall be not less than 28 days unless in the opinion of the Justifying Authority it is necessary for the provision of the information to be expedited.

(5) A notice served pursuant to paragraph (1) shall invite the person upon whom the notice is served to notify the Justifying Authority within 14 days of any grounds upon which the notice ought to be varied or withdrawn under paragraph (3).

#### **Inquiries and Hearings**

**17.**—(1) Without prejudice to any other power to hold an inquiry or other hearing, the Justifying Authority may cause an inquiry or other hearing to be held if it appears to him expedient to do so in connection with the exercise of any of his functions under these Regulations.

(2) In respect of any inquiry or other hearing held pursuant to paragraph (1)—

(a) if the inquiry or hearing is held in England or Wales, subsections (2) to (5) of section 250 of the Local Government Act 1972<sup>(6)</sup> (which contain supplementary provisions with respect to local inquiries held in pursuance of that section) shall apply as they apply to inquiries under that section, but as if—

(i) references to the person appointed to hold the inquiry included references to the Justifying Authority;

(ii) references to the Minister causing an inquiry to be held were references to the Justifying Authority;

(iii) the words “not being the property of a local authority” were deleted from paragraph (b) of subsection (2); and

(iv) the words “local authority or” in subsection (4) were deleted;

(b) if the inquiry or hearing is held in Scotland, subsections (2) and (4) to (8) of section 210 of the Local Government (Scotland) Act 1973<sup>(7)</sup> (which relate to the holding of local inquiries) shall apply as they apply to inquiries under that section, but as if—

(i) references to the person appointed to hold the inquiry included references to the Justifying Authority;

(ii) references to the Minister were references to the Justifying Authority; and

---

(6) 1972 c. 70; section 250, subsection (2) was amended by the Statute Law (Repeals) Act 1989 (c. 43) section 1 and Schedule 1; subsection (3) was amended by the Criminal Justice Act 1982 (c. 48), sections 37, 38 and 46; subsection (4) was amended by the Housing and Planning Act 1986 (c. 63), section 49(2), Schedule 12, part III.

(7) 1973 c. 65; section 210 was amended by the Criminal Procedure (Scotland) Act 1975 (c. 21), sections 289F and 289G (which were inserted into that Act by the Criminal Justice Act 1982 (c. 48), section 54) and the Housing and Planning Act 1986, Schedule 11, paragraph 39.

- (iii) the words “local authority or”, “any authority or” and “that authority or” in subsection (7) were deleted;
- (c) if the inquiry or hearing is held in Northern Ireland, paragraphs 1 and 3 to 8 of Schedule 8 to the Health and Personal Social Services (Northern Ireland) Order 1972<sup>(8)</sup> (which relate to the giving of evidence at, and the expenses incurred in relation to inquiries) shall apply as they apply in relation to an inquiry under that Schedule, but as if—
  - (i) references to the person appointed to hold the inquiry included references to the Justifying Authority; and
  - (ii) references to the Ministry were references to the Justifying Authority;
- (d) the Justifying Authority shall take such steps as he considers appropriate to publish or otherwise give notice of the time and place of the inquiry or hearing to any person likely to be affected by it.

### Consultation

**18.**—(1) Before making a justification decision, a determination under regulation 12 or serving a contravention notice under regulation 22, the Justifying Authority or Secretary of State (as the case may be)—

- (a) shall consult—
  - (i) the Health and Safety Executive<sup>(9)</sup>;
  - (ii) the Food Standards Agency<sup>(10)</sup>;
  - (iii) the National Radiological Protection Board<sup>(11)</sup>; and
  - (iv) where the class or type of practice involves a radioactive substance, the Environment Agency<sup>(12)</sup>, the Scottish Environment Protection Agency<sup>(13)</sup> and the Department of the Environment for Northern Ireland;
- (b) may consult any other person whom he considers it appropriate to consult;
- (c) shall take such steps as he considers appropriate to bring the proposed decision, determination or contravention notice to the attention of any person likely to be affected by it.

(2) Before exercising any function under Part 3 or under regulation 16, 17, 22, 26 or 27, the person proposing to exercise the function shall consult the other persons listed in regulation 6(1).

### Register

**19.**—(1) The Secretary of State shall maintain a register containing such particulars as he considers appropriate of—

- (a) any application made under regulation 9,10, or 12;
- (b) justification decisions and other determinations made under Part 3 or to which regulation 8 applies;
- (c) such other information as he considers appropriate.

(2) The Scottish Ministers, or a Northern Ireland department, or the National Assembly for Wales, having made a justification decision under regulation 9, 10 or 11 shall as soon as reasonably

<sup>(8)</sup> S.I.1972/1265 (N.I. 14), amended by S.R. 1976/281 and S.I. 1984/703 (N.I. 3).

<sup>(9)</sup> See section 10 of the Health and Safety at Work etc Act 1974 c. 37.

<sup>(10)</sup> See section 1 of the Food Standards Act 1999 c. 28.

<sup>(11)</sup> See section 1 of the Radiological Protection Act 1970 c. 46.

<sup>(12)</sup> See section 1 of the Environment Act 1995 c. 25.

<sup>(13)</sup> See section 20 of the Environment Act 1995.



practicable provide to the Secretary of State full particulars of that decision and such other information as he reasonably requires to perform his function under paragraph (1); and this paragraph shall apply to determinations to which regulation 8 applies as if they were justification decisions made by the relevant Justifying Authority on the entry into force of these Regulations.

- (3) The Secretary of State shall—
- (a) ensure that the register is open to inspection by members of the public free of charge at all reasonable hours; and
  - (b) afford to members of the public facilities for obtaining copies of entries, free of charge.

## PART 6

### *Personal Ornaments, Toys and Cosmetics*

#### **Addition of radioactive substances to personal ornaments, toys or cosmetics**

- 20.**—(1) No person shall –
- (a) knowingly or recklessly add any radioactive substance in the production of personal ornaments or toys; or
  - (b) knowingly or recklessly import or export any personal ornament, toy or cosmetic to which any radioactive substance has been added in its production.

(2) In paragraph 6 of Schedule 2 of the Toys (Safety) Regulations 1995<sup>(14)</sup> (which concerns radioactive substances in toys), for “Council Directive 80/836/Euratom shall apply”, substitute “This is without prejudice to regulation 20 of the Justification of Practices Involving Ionising Radiation Regulations 2004”.

## PART 7

### *Justification of classes or types of practice involving a medical exposure*

#### **Saving for medical practices**

**21.** Nothing in regulations 4(5) or 5(3) shall prevent anything permitted under regulation 6 of the Ionising Radiation (Medical Exposure) Regulations 2000<sup>(15)</sup>.

## PART 8

### *Enforcement and Offences*

#### **Contravention Notices**

**22.**—(1) For the purposes of this regulation and of regulation 23, a “relevant breach” means a contravention of regulation 4(5), 5(3) or 20; failure to comply with any condition imposed pursuant to regulation 11(1); or failure to comply with any requirement imposed pursuant to regulation 11(2) (b) or 16(1).

---

<sup>(14)</sup> S.I. 1995/204.

<sup>(15)</sup> S.I. 2000/1059, to which there is an amendment not relevant to these Regulations.

(2) If the Justifying Authority is of the opinion that a person has committed a relevant breach he shall serve a notice (in these Regulations referred to as a “contravention notice”) on that person.

(3) The Justifying Authority shall give notice of any contravention notice served pursuant to paragraph (2) to—

- (a) such of the persons listed in regulation 6(1) as are not the person serving the notice;
- (b) the Health and Safety Executive;
- (c) the Food Standards Agency;
- (d) the National Radiological Protection Board;
- (e) where the class or type of practice involves a radioactive substance, the Environment Agency and the Scottish Environment Protection Agency; and
- (f) any other person he considers appropriate.

(4) The contravention notice shall—

- (a) state that the Justifying Authority is of the opinion that the person has committed a relevant breach;
- (b) specify the matters constituting the contravention or failure to comply;
- (c) specify the steps that must be taken to remedy the contravention or failure to comply;
- (d) specify the period within which those steps must be taken;
- (e) specify the date on which the notice is to take effect;
- (f) invite the person upon whom the notice is served to notify the Justifying Authority within 14 days of any grounds upon which the notice ought to be varied or withdrawn under paragraph (5); and
- (g) not take effect before 28 days after the date of service of the notice, unless in the opinion of the Justifying Authority it is necessary for the notice to have immediate effect or otherwise to be expedited.

(5) The Justifying Authority may vary or withdraw any contravention notice by serving a further notice; and paragraph (3) and, in the case of a variation, paragraph (4) shall apply to that notice.

### **Enforcement Powers**

**23.** The Justifying Authority shall, for the purpose of determining whether a person has committed a relevant breach be entitled to exercise any of the powers specified in Schedule 1.

### **Offences and Penalties**

**24.—**(1) It is an offence for a person—

- (a) to fail without reasonable excuse to comply with any requirement imposed by a contravention notice served on him pursuant to regulation 22;
- (b) in providing any information under these Regulations, to—
  - (i) make a statement which he knows to be false or misleading in a material particular;
  - (ii) recklessly make a statement which is false or misleading in a material particular; or
  - (iii) produce or provide, or cause to be produced or provided, any document which he knows is false or misleading in a material particular.

(2) It is an offence for a person—

- (a) intentionally to obstruct the Justifying Authority, or a person to whom the Justifying Authority has (under regulation 27) delegated the enforcement powers under regulation 23, in the exercise or performance of his powers under regulation 23;
  - (b) without reasonable excuse—
    - (i) to fail to comply with any requirement imposed pursuant to regulation 23;
    - (ii) to fail or refuse to provide facilities or assistance or any information or to permit any inspection reasonably required by the Justifying Authority, or a person to whom the Justifying Authority has (under regulation 27) delegated the enforcement powers under regulation 23, in the exercise or performance of his powers under regulation 23;
    - (iii) to prevent any other person from appearing before or answering any question required to be answered by the Justifying Authority, or a person to whom the Justifying Authority has (under regulation 27) delegated the enforcement powers under regulation 23, in the exercise or performance of his powers under regulation 23;
  - (c) falsely to pretend to be a person to whom the Justifying Authority has (under regulation 27) delegated the enforcement powers under regulation 23.
- (3) A person guilty of an offence under paragraph (1) or (2) shall be liable—
- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

#### **Offences by bodies corporate etc.**

- 25.—(1) Schedule 2 applies to offences committed in England and Wales.
- (2) Schedule 3 applies to offences committed in Scotland.
  - (3) Schedule 4 applies to offences committed in Northern Ireland.

#### **Restriction on prosecutions**

26.—(1) Except as provided in regulation 27 and subject to paragraph (2), proceedings in respect of any offence under these Regulations shall not be instituted except by or with the consent of the Justifying Authority.

- (2) This regulation shall not apply in Scotland.

#### **Delegation of Enforcement Powers**

27.—(1) The Justifying Authority may delegate any or all of the following powers—

- (a) the powers under regulation 22 or 23;
- (b) the power to serve a notice under regulation 16, for the purpose of discharging any function delegated under sub-paragraph (a) of this regulation;
- (c) except in Scotland, the power to institute prosecutions under regulation 26;

and may make such delegation subject to conditions.

(2) The Justifying Authority may delegate the obligations arising under regulation 14(5) and 18, insofar as they arise out of the discharge or intended discharge of any function delegated under paragraph (1).

- (3) A delegation made under paragraph (1) is a determination to which regulation 14(6) applies.

8th July 2004

*Elliot Morley*  
Minister of State  
Department for Environment, Food and Rural  
Affairs