

EXPLANATORY MEMORANDUM

The Justification of Practices Involving Ionising Radiation Regulations 2004

SI 2004 No 1769

This explanatory memorandum is laid before Parliament by Command of Her Majesty. This memorandum contains information for the Joint Committee on Statutory Instruments.

Department responsible:

Department for Environment, Food and Rural Affairs.

Description:

These regulations, which implement European directive obligations, provide a framework in which justification decisions will be made. Justification involves weighing the overall benefits of classes or types of practices which might result in the exposure of people to ionising radiation against the harm likely to be caused by the radiation exposure. New classes or types of practice need to be justified in advance of their being first adopted; existing classes or types of practice (ie those which were being undertaken before 13 May 2000) may be reviewed to see if they are justified or not whenever new and important evidence about their efficacy or consequences is acquired. These regulations also prohibit the addition of radioactive materials to certain goods, and the import or export of those goods.

Matters of special interest to the Joint Committee on Statutory Instruments:

These regulations, transposing requirements in a Directive, are made under section 2(2) of the European Communities Act 1972. The Directive requires generic justification decisions, which determine whether a whole class of practice is justified. The Department considers that such generic decisions would be legislative in nature, and that to purport to confer the power to make the decisions themselves in these regulations would offend against the rule, in Schedule 2 para 1(1)(c) of the Act, prohibiting the conferring of any power to legislate by means of subordinate instrument.

To transpose the Directive, therefore, without offending against this rule, the regulations indicate that justification decisions themselves will be made (by the Secretary of State or Devolved Administrations) by means of further regulations, which are made using a power that derives from somewhere other than these justification regulations. They define a justification decision in those terms, while expressly avoiding conferring that power (regulation 14(1)). In practice the source of that power will be section 2(2) ECA 1972 (which powers already exist for England, Scotland and Northern Ireland - for Wales the necessary transfers of functions and designations are yet to be made).

The present regulations complement this by creating the surrounding framework, which prohibits unjustified practices, and creates offences, application procedures, enforcement mechanisms and so on.

Legislative Background:

The regulations transpose into law the justification requirements of the Basic Safety Standards Directive (Council Directive 96/29/Euratom of 13 May 1996 which lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation):

- Articles 6(1) and 6(2), which deal with justification of new classes or types of practice involving exposure to ionising radiation, and the review of existing practices;
- Article 6(5), in part, which completely prohibits the addition of radioactive substances to certain goods and their import or export (the rest of this article is transposed elsewhere - see the transposition note);

and they also preserve the saving in Article 3(1) (a) of Council Directive 97/43/Euratom of 30 June 1997 (on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom) which permits individually justified medical exposures where the class in general is not justified.

A Transposition Note is attached.

Extent:

The instrument applies to the UK.

Policy Background:

Justification is one of the key principles of radiological protection established by International Commission on Radiological Protection on which the radiological framework of the EU and the UK is based. Exposure to ionising radiation can lead to detrimental health effects in human beings. The Directive sets out requirements designed for the protection of workers and the general public against the dangers of ionising radiation without unduly limiting the beneficial uses of the practices giving rise to radiation exposure. Justification decisions are not new although these Regulations require a generic assessment of classes or types of practice, rather than site-specific assessment of individual practices. Previously, justification decisions were taken on a site-by-site basis by the Environment Agency in respect of England and Wales. In Scotland, justification decisions were taken by the Scottish Environment Protection Agency. There have been no justification decisions in Northern Ireland. There has been no public interest in the Regulations.

Impact:

Regulatory Impact Assessment attached.

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Regulatory Impact Assessment

1. TITLE: THE JUSTIFICATION OF PRACTICES INVOLVING IONISING RADIATION REGULATIONS 2004

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

(i) The objective:

To transpose into national legislation the following justification requirements of Council Directives 96/29/Euratom and 97/43/Euratom:

- Article 6(1) of the 1996 Directive which requires that all new classes or types of practice resulting in exposure to ionising radiation are justified in advance of being first adopted or first approved;
- Article 6(2) of the 1996 Directive which allows an existing class or type of practice to be reviewed whenever new and important evidence is acquired;
- Article 3(1)(a) and (b) of the 1997 Directive which provides for generic types of medical practice to be justified in advance and an exemption for individual medical practices which may be justified on a case-by-case basis even though the type of practice may not be justified at the generic level.

The regulations will also transpose Article 6(5) (in part) of the 1996 Directive which is concerned with the prohibition of the deliberate addition of radioactive substances to foodstuffs, toys, cosmetics and personal ornaments and the import and export of these goods.

These regulations will apply to the UK.

(ii) The background:

The revised Basic Safety Standards (BSS) Directive 96/29/Euratom lays down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation and has been implemented in the UK through a number of different Acts and Regulations, including the Radioactive Substances Act 1993 (RSA 93) and the Ionising Radiations Regulations 1999 (and the Ionising Radiations Regulations (Northern Ireland) 2000). The 1997 Directive supplements the 1996 Directive and lays down general principles for the health protection of individuals against the dangers of ionising radiation in relation to medical exposure. The Ionising Radiation (Medical Exposures) Regulations 2000

(and the Ionising Radiation (Medical Exposures) Regulations (Northern Ireland) 2000) is the main piece of implementing legislation.

Article 6 of the 1996 Directive requires Member States to ensure that all new classes or types of practice resulting in exposure to ionising radiation are justified in advance of being first adopted or first approved. Justification takes account of economic, social and other benefits in relation to the potential health detriment that the new class or type of practice might cause. The Directive also allows Member States to review the justification for an existing class or type of practice whenever new and important evidence about the efficacy or consequences of that practice is acquired.

The system of radiological protection in the UK is based upon the requirements of the Basic Safety Standards Directive which in turn is based upon the recommendations of the International Commission on Radiological Protection (ICRP). Prior to the 1996 Directive, justification decisions were taken on a site-by-site basis by the regulators when considering individual applications under the RSA 93. These regulations introduce procedures for justification decisions to be made on a generic basis and for the review of existing practices in changed circumstances.

The requirements of Article 6(5) of the 1996 Directive relating to foodstuffs, has been transposed by the Food Safety Act 1990. Because we know of no circumstances where radioactive substances are added to personal ornaments, cosmetics or toys or that such articles are imported into the UK this aspect of the regulations is not addressed any further in the RIA.

(iii) Risk assessment

Radiation is present in the environment as a result of natural processes and man's technological developments. Because of the assumption that there is no safe level of radiation the principle of justification means that no practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. This is only the first stage in the legal permission process which provides a high level of radiological protection for workers and members of the public.

(iv) Business sectors affected

Industries using radiation range from nuclear power plants to hospitals, universities, and research laboratories. Many other industries in a variety of sectors use radioactivity for diagnostic, therapeutic, industrial, teaching and research purposes. The transport sector is also affected.

(v) Issues of equity and fairness

No issues of equity or fairness have been identified.

3. OPTIONS

The UK is legally obliged to fully implement Directives and there is little scope for national discretion in the way this is implemented. Regulations are being

used on the basis of legal advice. In the Health and Safety Commission's consultative document ("Proposals for Revised Ionising Radiations Regulations and Approved Code of Practice", CD127), published on 25 February 1998, the question whether the necessary implementing legislation should be included in the revised regulations or in freestanding legislation was posed specifically. Although the preferred option at that time was the inclusion of justification in the revised Ionising Radiations Regulations, in the light of subsequent legal advice, it is now considered more appropriate for it to be a new freestanding instrument.

4. BENEFITS

The prevention of practices being undertaken which do not produce sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes is an important aspect of the protection of the health of workers and the general public against the dangers arising from ionising radiation. These benefits have been enjoyed by the UK population through the site-by-site justification process previously carried out by the regulators under RSA 93. The main benefit of generic justification - which is undertaken once in a more formal system - over individual site-by-site justification is that it will be less onerous for industry. Clearance of the "justification" hurdle does not relieve an operator of the need to apply for and obtain all other necessary permissions and authorisations before he can start a new practice. The regulations will also establish a transparent system for all justification decisions.

5. COSTS FOR BUSINESS, CHARITIES AND VOLUNTARY ORGANISATIONS

(i) Compliance costs

The regulations do not introduce a new burden because under the previous Basic Safety Standards Directive decisions in respect of justification were required to be taken in respect of individual uses of particular classes or types of practice. What is now required to be justified is a particular class or type of practice, not individual uses. Generic justification will be less onerous for industry. It is not foreseen that the associated costs of getting a practice justified will increase significantly. There may be additional calls on government in administering the provisions of a more formal procedure.

Some additional regulatory effort may be required because of the formality of administering the provisions of the proposed regulations. The assessment of a particular case for determination would include the call for information, the preparation of the case for justification, consultation with interested parties and other government departments, the determination of the case and, in the case of a major determination, the conduct of an inquiry. Although formalised by the regulations none of these is in fact new.

Charities and voluntary organisations are not likely to be affected by the regulations.

(ii) Costs for a typical business

The principal compliance costs for an organisation submitting a case for determination are likely to be:

- preparation of justification case document and provision of information specified by the Justifying Authority;
- legal costs and representation at a public inquiry, if required.

The wide range of cases that could arise – from a simple existing determination to a new build type of nuclear plant application – makes it impossible to provide any meaningful costs. There will also be a range of costs involved to industry when an existing practice is reviewed.

6. CONSULTATION WITH SMALL BUSINESSES: the “small firms impact test”

The regulations should not impose any new significant compliance costs on small businesses because they have previously had to obtain site-by-site justification under RSA 93. It is possible that an innovative practice belonging to a new class or type of practice could be the result of an entrepreneurial small business but it is impossible to provide any meaningful costs. During the consultation no comments were received from small businesses about the cost implications of the regulations. It is expected, however, that as the regulations relate to generic practices the majority of applications to the Justifying Authority will originate from large operators within the nuclear industry or from organisations representing small users of radioactivity.

7. COMPETITION ASSESSMENT

The generic regulations do not impose a new burden on industry and will therefore not affect competition in the relevant markets.

8. ENFORCEMENT AND SANCTIONS

The Secretary of State and Devolved Administrations, or regulators designated by them, will enforce the regulations. No new regulatory bodies are proposed but because of the wide range of applications using radioactivity the appropriate regulator will vary on a case by case basis and may include the Health and Safety Executive, the Food Standards Agency, Trading Standards Officers and the Environment Agencies.

Non-compliance with the requirements of the regulations will lead to the serving of a contravention notice. Failure to comply with this, without a reasonable excuse, will constitute an offence, subject to the penalties set out in the regulations – a maximum fine on summary conviction of £5,000; a maximum imprisonment on summary conviction of 3 months; a maximum length of imprisonment on indictment of 2 years.

9. MONITORING AND REVIEW

The BSS Directive is revised periodically to reflect revised ICRP recommendations.

10. CONSULTATION

(i) Within Government

These regulations have been drawn up in consultation with other government departments and agencies including the Health and Safety Executive, Department of Trade and Industry, Department of Health, Food Standards Agency, Ministry of Defence, Department for Constitutional Affairs, Department for Transport, Department for Education and Skills, the Devolved Administrations and the Environment Agencies.

(ii) Public consultation

A three month written consultation was undertaken between January and April 2004. The document was also available on the Defra website. Those consulted included industry, regulators, professional bodies, environmental groups and interested individuals. Twenty-eight responses were received, the majority of which supported the regulations. Many of the amendments proposed by respondents have been addressed in the regulations themselves or in the accompanying guidance.

11. SUMMARY

These regulations are necessary to implement the justification aspects of the BSS Directive. The principle of justification has previously been undertaken as part of the RSA 93 application process on a site-by-site basis. They will not therefore introduce a new burden on industry, the regulators or government. However, the size of the burden may increase on some concerned because of the formalised procedures that need to be put in place. Overall, it is believed that the introduction of generic justification will establish a transparent system that will be less onerous for industry.

12. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister: Elliot Morley

Date: 8 July 2004

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TRANSPOSITION NOTE

Directive(s) being transposed:

Council Directive 96/29/Euratom (OJ No. L159, 29.6.96, p.1) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation:

- Article 6(1)
- Article 6(2)
- Article 6(5) (in part)

Council Directive 97/43/Euratom on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom:

- Article 3

Directive 96/29/Euratom			
Article	Objectives	Implementation	Responsibility
6(1)	Prior justification of new practices involving exposure to ionising radiation.	Reg. 4(5)- prohibits carrying out new (unjustified) practices. Reg. 5(2) permits practices once justified. Reg 5(3) prohibits practices after a finding that the class is not justified. Reg 4(3) and 14(1) provides that a justification decision, for these purposes, is made by regulations. Reg. 9 deals with applications.	The “Justifying Authority”, i.e. such of the Devolved administrations as is competent to make the decision in devolved subject areas, and the appropriate Secretary of State in relation to England or non-devolved areas.
6(2)	Existing practices may be reviewed as to justification if there is new and important evidence about their efficacy or consequences.	Reg. 10. Reg 5(3) prohibits practices after a finding that the class is not justified.	The Justifying Authority (see above).

6(5)	Prohibits (a) addition of radioactive substances to:- foodstuffs, toys, personal ornaments, cosmetics; and (b) import/export of such goods.	Reg. 20, in relation to personal ornaments and toys, and import/export of cosmetics. Addition to cosmetics is covered in Schedule 3, Part 1 of the Cosmetic Products (Safety) Regulations 2003 (SI 2003/835), which also implements Directive 2002/34/EC (the 26th Amendment to the Cosmetics Directive); foodstuffs are covered by the Food Safety Act 1990 (c.16) sections 7 and 18(1)(c).	The Justifying Authority or persons delegated by the Justifying Authority (reg. 27), e.g. trading standards officers.
Council Directive 97/43/Euratom			
3	Permits individually justified medical exposures, if the class of practice has not generally been justified.	Reg 21 preserves the main implementing provision, reg. 6 of the Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000/1059).	Medical practitioners administering ionising radiation; Local Research Ethics Committee; the 'appropriate authority' (Secretary of State/Devolved Administrations).