EXPLANATORY MEMORANDUM TO

THE JUSTIFICATION OF PRACTICES INVOLVING IONISING RADIATION (AMENDMENT) REGULATIONS 2018

2018 No. 430

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Business, Energy and Industrial Strategy (the "Department") and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This Instrument amends the Justification of Practices Involving Ionising Radiation Regulations 2004 (the "2004 Regulations") in order to transpose new requirements contained in the European Council Directive 2013/59/Euratom[1], commonly referred to as the Basic Safety Standards Directive (the "Directive"). The Directive lays down basic safety standards for the protection against the dangers arising from exposure to ionising radiation.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

4.1 The Instrument is made principally in order to transpose new requirements set out in the Directive. The Directive consolidates and updates five directives and a European Commission recommendation. In particular the Directive updates and simplifies the 1996 Basic Safety Standards Directive (Council Directive 96/29/Euratom[2]). The Directive incorporates subsequent publications from the International Commission on Radiological Protection (ICRP), which were published in 2007[3], and harmonises the Euratom regime with the International Basic Safety Standards issued by the International Atomic Energy Agency (IAEA)[4]. The deadline for transposition of the Directive is 6 February 2018.

4.2 The Directive covers radiation protection from different perspectives: workers ("occupational exposures"), the public ("public exposures") medical patients ("medical exposures") and emergency preparedness and response. Most of the

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0059
[2] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1502202246211&uri=CELEX:31996L0029
[3] http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103
[4] http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf

requirements of the Directive are already implemented in existing UK legislation. This Instrument is necessary to transpose new requirements contained in the Directive concerning justification[5] that are not covered by the existing UK legislation.

4.3 The 1996 Basic Safety Standards Directive was transposed, so far as the majority of the requirements relating to justification were concerned, by the 2004 Regulations. The 2004 Regulations set out a framework for the making of justification decisions, as well as procedural requirements relating to those decisions and prohibitions on certain activities involving radioactive substances. Under the 2004 Regulations, justification decisions are made by the Secretary of State or, in some cases, by the Devolved Administrations (together, the "Justifying Authority").

4.4 The Instrument amends the 2004 Regulations. It is one of a series of instruments which will implement the requirements of the Directive.

4.5 The Department is responsible for transposing the Directive's requirements on justification, public exposures and emergency preparedness and response. The Instrument is one of a set of four that the Department is making to implement the justification and public exposure aspects of the Directive. The other instruments in the set are:

- The Environmental Permitting (England and Wales) (Amendment) (No. 2) Regulations 2018;[6]
- The Radioactive Contaminated Land (Enabling Powers and Modification of Enactments) (Amendment) (England) Regulations 2018;[7]
- The Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018.[8]

4.6 The Instrument transposes the majority of the Directive's requirements relating to justification, but a number of other pieces of legislation implement specific aspects in specific contexts.[9]

4.7 The European Scrutiny Committees were provided with an Explanatory Memorandum (14450/11) on 19 October 2011 concerning a Commission proposal for a Council Directive updating the basic safety standards for protection against the dangers arising from exposure to ionising radiation. Following some correspondence between the Committees and the Minister, the Explanatory Memorandum was cleared by the Lords European Union Select Committee on 22 May 2013 and by the Commons European Scrutiny Select Committee on 2 July 2013.

4.8 A Transposition Note is submitted with this Explanatory Memorandum.

5. Extent and Territorial Application

5.1 The extent of this instrument is the United Kingdom.

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[5] The concept of justification in the context of radiological protection is explained at paragraph 7.3.
[6] 2018/428
[7] 2018/429
[8] This instrument will be made on a separate date.
[9] The other pieces of legislation are the Food Safety Act 1990, the Animal Feed (Basic Safety Standards) (Scotland) Regulations 2018/15 (Scottish SI), the Animal Feed (Basic Safety Standards) (Wales) Regulations 2018/40, the Animal Feed (Basic Safety Standards) (Northern Ireland) 2018/16, the Animal Feed (Basic Safety Standards) Regulations 2018, the Ionising Radiation (Medical Exposure) Regulations 2017/1322 and the Ionising Radiation Medical Exposure) Regulations (Northern Ireland) 2018/17.

5.2 The territorial application of this instrument is the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the EU and all rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

7.2 The policy objective is to ensure that members of the public are protected from exposure to ionising radiation in line with the requirements of the Directive and that the required standard of protection is achieved efficiently.

7.3 Justification is the first step in the regulatory process for ionising radiation. Before any new class or type of practice involving ionising radiation (such as a new type of nuclear reactor) can be introduced in the UK, the Government must first assess it to determine whether the individual or societal benefits outweigh the health detriment it may cause[10].

7.4 This process forms a fundamental part of the radiological protection scheme set out in the Directive. The aim of the Directive is to update and simplify existing arrangements for radiological protection by bringing the subject matter covered by five Directives and a European Commission recommendation into one single Directive. It also incorporates the latest recommendations from the International Commission on Radiological Protection published in 2007 and harmonises the Euratom regime with the Basic Safety Standards of the International Atomic Energy Agency.

7.5 Many of the requirements of the Directive are already part of the UK's health and safety regime; in the case of justification, many of the relevant requirements are already provided for by the 2004 Regulations. However, the Instrument is necessary to ensure that the UK complies fully with the justification elements of the Directive; this in turn will help to ensure that the UK continues to be considered a reliable partner internationally with whom to trade nuclear materials, services and skills.

7.6 The key changes which the Instrument makes to the 2004 Regulations are:

[10] The term "practice" includes a wide range of activities including nuclear power generation and supporting activities, the use of radioactive materials or radiation sources for industrial applications such as radiography or process control, the operation of equipment that emits radiation in a public or occupational setting, and the use of radioactive materials in various types of products, research and educational activities. The Directive refers to classes or types of practice. This emphasises the underlying principle that justification is to be applied generically rather than at the level of individual uses of a practice; various different practices can exist within one class or type of practice.

- Activation of materials: the amendments prohibit practices involving the activation of materials[11] used in toys or personal ornaments where that may increase their radioactivity. They also prohibit the import and export of such products and materials.
- Consumer products: the amendments create new requirements relating to consumer products whose intended use would constitute a practice. In particular, persons intending to manufacture or import consumer products whose intended use is likely to belong to a new class or type of practice involving ionising radiation must first apply to the Justifying Authority for a justification decision in respect of that class or type. The amendments also set out specific information that such persons must provide with their applications and specific factors that the Justifying Authority must assess in making justification decisions in respect of those applications.
- Non-medical imaging exposure: the amendments introduce new requirements for persons carrying out non-medical imaging exposures not using medical radiological equipment ("imaging practices")[12]. The amendments include a specific determination process for new imaging practices; a requirement to ensure the individual justification of exposures of persons to radiation as part of imaging practices or to carry out regular reviews of the relevant imaging practice; the requirement to obtain an approval containing conditions for the carrying out of an imaging practice before commencing that practice; and information and consent requirements that apply to the carrying out of imaging practices.
- The Justifying Authority: the amendments require the Justifying Authority to be functionally separate from any other person concerned with the promotion or utilisation of practices in relation to which the Justifying Authority is exercising functions under the 2004 Regulations.
- Justification decisions in specific contexts: the amendments set out factors which the Justifying Authority must take into account in making justification decisions in respect of classes or types of practice involving both occupational and public exposures and those involving medical exposures.
- Inspections: the amendments require 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.
- Application of criminal offences to the Crown: the amendments provide that no contravention by the Crown of any of the provisions of the 2004 Regulations makes it criminally liable. Instead, the appropriate remedy in respect of the Crown is a declaration by the court that the relevant act or omission of the Crown is unlawful.
- Review: the amendments insert a statutory review clause into the 2004 Regulations in line with the Small Business, Enterprise and Employment Act 2015.

[11] Activation is the process of transforming a non-radioactive substance into a radioactive substance by irradiating it with particles or high-energy protons.
[12] Examples of imaging practices include the use of x-ray machines to scan suspected smugglers at ports and airports and to scan those suspected of smuggling contraband items into prisons.

Consolidation

7.7 The Department does not intend to consolidate the relevant legislation at this time.

8. Consultation outcome

8.1 The Department conducted a UK-wide public consultation on the proposals for transposing the public exposures and justification requirements in the Directive from 5 October to 15 November 2017 (six weeks). The consultation included a draft of the proposed amendments to the 2004 Regulations. The consultation asked 12 substantive questions. No question specifically related to the proposed amendments to the 2004 Regulations, but the 12th question asked for general comments on all of the proposals covered by the consultation. Responses relevant to the proposed amendments to the 2004 Regulations were provided under this 'general' question.

8.2 The Department received 48 consultation responses from professional bodies, industry associations, private and public sector organisations engaged in radioactive substances activities and from individual respondents from across the UK. The majority of consultees supported the proposals.

8.3 Three of the responses to the consultation related specifically to the proposed amendments to the 2004 Regulations. Two of the responses suggested that the amendments to the 2004 Regulations should go beyond what is required by the Directive. It was decided that the suggested changes would be inconsistent with the Department's approach of implementing only what is required by the Directive (that is, they would amount to 'gold plating') and that the circumstances did not warrant such inconsistency in this case. Those changes will therefore not be taken forward by the Department. A third response noted the need for the Department to update and clarify the accompanying guidance to take new definitions and other changes into account, which has already been done.

8.4 The full Government response to the consultation can be found on the GOV.UK website.

9. Guidance

9.1 The Department has updated the guidance on the application and administration of the 2004 Regulations to reflect the changes made by the Instrument. This guidance describes the principle of justification, the main provisions of the regulations and how to make an application to the Justifying Authority. It also includes an annex containing those classes or types of practice involving ionising radiation that existed prior to the implementation deadline for the Directive. These classes and types are treated as 'existing' classes/types of practice and do not require a new justification decision before they can be carried out in the UK. The guidance document is available at: https://www.gov.uk/government/publications/the-justification-of-practices-involving-ionising-radiation-regulations-2004-guidance-on-their-application-and-administration

10. Impact

10.1 There is minimal impact on business, charities or voluntary bodies. There will be some small additional administrative requirements (and therefore costs) for those carrying out imaging practices, but as all such operators in the private sector will be

acting on behalf of the public sector (i.e. contracted-out prisons), the impact on private sector businesses will be minimal.

10.2 There is minimal impact on the public sector. The Government will be required to seek to identify imaging practices which may incur the need for some additional administrative resource and therefore cost. Additionally, the public sector is considered to be the sole operator of imaging practices (in prisons operated by or on behalf of Her Majesty's Prisons and Probation Service's and as part of the Border Force's operations at ports and airports) and the introduction of some administrative requirements will incur some costs.

10.3 An Impact Assessment (IA) is not attached to this memorandum as the measures here have a net direct impact on business or civil society organisations of less than £5 million annually and therefore qualify for a fast track process, which does not require an IA for better regulation purposes.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses.

11.2 The consultation document was sent to businesses and business organisations, including those that represent small businesses

11.3 No specific action is proposed to minimise regulatory burdens on small businesses. The basis for the final decision on what action to take to assist small business is in line with the principle of justification: the Government must determine whether the individual or societal benefit of a new class or type of practice involving ionising radiation outweighs its potential detriment to health. To maintain safe practice across all businesses, each must have the same opportunity and requirements to apply for a justification decision, regardless of their size.

12. Monitoring & review

12.1 The Secretary of State must, from time to time, carry out a review of the regulatory provisions in the 2004 Regulations and publish a report setting out the conclusions of the review. The first report will be published by 2023 (within five years of the Instrument coming into force) and subsequent reports will be published at intervals not exceeding five years.

13. Contact

13.1 Joseph Tyrrell at the Department for Business, Energy and Industrial Strategy can answer any queries regarding the Instrument. He can be contacted by telephone (020 7215 0617) or email (joseph.tyrrell@beis.gov.uk).