EXPLANATORY MEMORANDUM TO

THE IONISING RADIATIONS REGULATIONS 2017

2017 No. 1075

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions (DWP) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument sets out a framework to ensure that occupational exposures to ionising radiations are kept as low as is reasonably practicable. It transposes the occupational elements of Council Directive 2013/59/EURATOM[1] laying down basic safety standards for protection against the dangers arising from exposure to ionising radiations.

2.2 The instrument revokes The Ionising Radiations Regulations 1999 (1999/3232)[2].

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 negative resolution 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 There have been specific legislative controls on ionising radiations since the late 1960s. Four sets of Regulations were consolidated into the Ionising Radiations Regulations 1985[3] which were superseded by the Ionising Radiations Regulations 1999[4]. In addition, The Management of Health and Safety at Work Regulations 1999[5] covers the general duties which employers have towards employees and members of the public, and employees have to themselves and to each other.

4.2 The Ionising Radiations Regulations 2017 are being introduced to transpose the occupational elements of Council Directive 2013/59/EURATOM of 5 December 2013. The Directive lays down basic safety standards for protection against the dangers arising from exposure to ionising radiations. Many of the requirements of the Directive are already part of the UK's health and safety regime. However, these new

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013L0059
[2] http://www.legislation.gov.uk/uksi/1999/3232/contents/made
[3] http://www.legislation.gov.uk/uksi/1985/1333/contents/made
[4] http://www.legislation.gov.uk/uksi/1999/3232/contents/made
[5] http://www.legislation.gov.uk/uksi/1999/3242/contents/made

Regulations are necessary to give effect to some requirements of the Directive that go further than existing controls covered by The Ionising Radiations Regulations 1999.

4.3 The Directive is wide-ranging, covering radiological protection from a number of different perspectives, including occupational, medical, public and emergency preparedness and response. While this instrument transposes only the requirements of the Directive that relate to occupational exposures, a series of other instruments will transpose the provisions as they relate to medical, public and emergency preparedness and response. These other instruments, which will be laid in Parliament in the coming months, will each be covered by a separate Explanatory Memorandum.

4.4 A Transposition Note and Scrutiny History are submitted with this Explanatory Memorandum.

5. Extent and Territorial Application

5.1 The extent of this instrument is Great Britain.

5.2 The territorial application of this instrument is Great Britain and extends to premises and activities specified in the Health and Safety at Work Act etc. 1974 (Application outside Great Britain) Order 2013[6].

5.3 The Health and Safety Executive (Northern Ireland) and the Government of Gibraltar are transposing the requirements of the Directive via their own legislative systems.

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 The policy objective is to transpose the requirements of Directive 2013/59/EURATOM by its implementation date, 6 February 2018. The aim of the Directive is to update and simplify existing arrangements for radiological protection by bringing the following five directives and European Commission recommendation into one directive:

- Basic Safety Standards, Directive 96/29/Euratom[7]
- Medical Exposures, Directive 97/43/Euratom[8]
- Outside Workers, Directive 90/641/Euratom[9]
- Control of high activity sealed radioactive sources and orphan sources 2003/122/Euratom[10]
- Public Information Directive 89/618/Euratom[11]
- Radon, Commission Recommendation 90/143/Euratom[12]

[6] http://www.legislation.gov.uk/uksi/2013/240/contents/made
[7] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1502202246211&uri=CELEX:31996L0029
[8] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31997L0043
[9] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31990L0641
[10] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32003L0122
[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0618:EN:HTML
[12] http://eur-lex.europa.eu/legal-content/SV/ALL/?uri=CELEX%3A31990H0143

It also incorporates the latest recommendations from the International Commission on Radiological Protection (ICRP) published in 2007[13], and harmonises the EU regime with the Basic Safety Standards of the International Atomic Energy Agency (IAEA).

7.2 Ionising radiations occur either as electromagnetic rays, such as X-rays and gamma rays, or as particles such as alpha and beta particles, and are used in a diverse range of industries and sectors including medical, nuclear, manufacturing and construction. Ionising radiation is also found in naturally occurring radioactive sources, such as radon. People can be exposed to ionising radiations both internally and externally. External exposure can be from a radioactive material or a radiation generator such as an x-ray machine. Internal exposure can occur via inhalation or ingestion of a radioactive substance. Although its use brings considerable benefits, it can give rise to serious harmful health effects, so exposure must be properly managed.

7.3 The key measures set out in the instrument to control occupational exposures are:

- carrying out a radiation prior risk assessment to consider potential doses;
- dose limits for those working with radiation - these are legal limits that must not be exceeded;
- taking steps to restrict exposure via use of appropriate control measures;
- designation of areas where high exposures are possible, control of access into these areas, and ensuring specific rules are in place to govern work activity; and
- ensuring that employers who work with ionising radiations engage the services of a Radiation Protection Adviser (RPA) to provide specialist advice on compliance with the regulations.

7.4 The Regulations are being implemented five weeks ahead of the transposition deadline so that businesses can continue calculating exposures to ionising radiations on a calendar year basis. Implementing on the transposition deadline of 6 February would mean two dose limits would apply in the calendar year 2018, which would cause confusion and could have health and safety implications for workers, and introduce additional costs to business.

7.5 Modernisation of the Regulations is in line with the Government's better regulation policy and principles. It will continue to make the legislative framework simpler and easier to understand, while strengthening the standards of protection for those in the workplace or affected by work activities.

7.6 On 23 June 2016, the EU referendum was held and the people of the United Kingdom voted to leave the European Union. The Government respected the result and triggered Article 50 of the Treaty on European Union on 29th March 2017 to begin the process of exit. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will also 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.

[13] http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103

8. Consultation outcome

8.1 The consultation ran for 8 weeks and the length of the consultation period reflected the significant amount of stakeholder engagement carried out throughout the transposition process. This included HSE establishing a working group consisting of representatives from across all sectors which might be affected. The group worked with HSE to help develop the transposition approach and estimate the impacts of implementing the Directive on their individual sectors.

8.2 The consultation document[14] was made available on the HSE website and stakeholders were alerted to its publication. The consultation sought responses on specific aspects of the proposed transposition approach, including feedback on the draft Regulations and suggested changes to the Approved Code of Practice.

8.3 HSE received 129 responses from a wide range of sectors. They showed around half of respondents supported the implementation of the Directive as proposed. The main concerns raised related to the introduction of a three-tiered system of regulatory control (for notification, registration and consent of radiation practices), particularly the proposed renewal periods. HSE took account of this feedback and removed the proposal for renewals from the regulations. The overwhelming majority of stakeholders agreed with early implementation of the regulations.

8.4 The responses provided a large number of useful and detailed comments on the draft Approved Code of Practice, which has been updated to ensure it is easy to understand to minimise familiarisation costs to business. HSE also set up a separate working group with stakeholder representation to specifically review the Approved Code of Practice and associated guidance. An analysis[15] of the consultation responses is available on the HSE website.

9. Guidance

9.1 HSE has developed guidance on the new arrangements which will provide practical advice and will help industry and enforcing authorities.

10. Impact

10.1 The impact on business, charities or voluntary bodies is £5.8 million.

10.2 The impact on the public sector is £13.1 million.

10.3 An Impact Assessment is submitted with this Explanatory Memorandum and will be published on the legislation.gov.uk website.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses. HSE is introducing the Regulations to coincide with the calendar year assessment of doses, a system that has been in place for over 30 years. This will benefit small businesses as keeping the current cycle of assessment will mean that no additional costs will be incurred. It will also prevent confusion over which dose limits should be used; this will help small businesses comply with the Regulations.

[14] http://www.hse.gov.uk/consult/condocs/cd282.htm
[15] http://www.hse.gov.uk/consult/condocs/cd282.htm

12. Monitoring & review

12.1 The Regulations include a review clause and will be reviewed in line with government policy, i.e. before the fifth anniversary of the Regulations. The first report of this review is to be published before 1 January 2023.

13. Contact

13.1 Clare McNicholas at the Health and Safety Executive (Tel: 0203 028 3972 or email clare.mcnicholas@hse.gov.uk) can answer any queries regarding the instrument.