

EXPLANATORY MEMORANDUM TO
THE IONISING RADIATION (BASIC SAFETY STANDARDS) (MISCELLANEOUS
PROVISIONS) REGULATIONS 2018

2018 No. 482

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 transposes new requirements contained in the European Council Directive 2013/59/Euratom¹, commonly referred to as the Basic Safety Standards Directive (“the Directive”), which lays down basic safety standards for 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 the 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 This Instrument transposes new requirements in the Directive, which has a transposition date of 6 February 2018.

4.2 The Directive updates and simplifies existing arrangements for protection against the dangers arising from exposure to ionising radiation by consolidating 5 directives and a European Commission recommendation into one directive:

- Basic Safety Standards, Directive 96/29/Euratom²
- Medical Exposures, Directive 97/43/Euratom³
- Outside Workers, Directive 90/641/Euratom⁴
- Control of high activity sealed radioactive sources and orphan sources Directive 2003/122/Euratom⁵
- Public Information Directive 89/618/Euratom⁶

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0059&from=EN>

² <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1502202246211&uri=CELEX:31996L0029>

³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31997L0043>

⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31990L0641>

⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32003L0122>

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0618:EN:HTML>

- Radon, Commission Recommendation 90/143/Euratom.⁷

As such, most of the requirements of the Directive are already implemented in existing United Kingdom legislation through various statutory regimes. This Instrument is necessary to transpose new requirements contained in the Directive concerning public exposures that do not fit within existing statutory regimes. The Directive also incorporates recommendations from the International Commission on Radiological Protection (ICRP), which were published in 2007⁸, and harmonise the Euratom regime with the International Basic Safety Standards issued by the International Atomic Energy Agency⁹.

- 4.3 The Directive covers radiation protection for workers, members of the public and medical patients against the dangers arising from ionising radiation.
- 4.4 This Instrument is one of a set of four which are being made by the Department to transpose the public exposures and justification requirements of the Directive. The other instruments are:
- the Environmental Permitting (England and Wales) (Amendment) (No. 2) Regulations 2018¹⁰;
 - the Radioactive Contaminated Land (Enabling Powers and Modification of Enactments) (England) (Amendment) Regulations 2018¹¹;
 - the Justification of Practices Involving Ionising Radiation (Amendment) Regulations 2018¹².
- 4.5 The European Scrutiny Committees were provided with an Explanatory Memorandum 14450/11 on 19 October 2011 concerning the Commission's proposal for a Council Directive updating the basic safety standards for protection against the dangers arising from exposure to ionising radiation. Following 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.
- 4.6 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.
- 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 <http://eur-lex.europa.eu/legal-content/SV/ALL/?uri=CELEX%3A31990H0143>

⁸ <http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103>

⁹ http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf

¹⁰ S.I. 2018/428 - http://www.legislation.gov.uk/uksi/2018/428/pdfs/ukxi_20180428_en.pdf

¹¹ S.I. 2018/429 - http://www.legislation.gov.uk/uksi/2018/429/pdfs/ukxi_20180429_en.pdf

¹² S.I. 2018/430 - http://www.legislation.gov.uk/uksi/2018/429/pdfs/ukxi_20180430_en.pdf

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 United Kingdom 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 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 United Kingdom has left the EU.
- 7.2 The Directive incorporates updated scientific methodologies and new learning in the field of radiological protection. The transposition of the Directive is important as the standards within it are internationally recognised as best practice and the United Kingdom is committed to maintaining the highest possible safety standards in relation to ionising radiation.
- 7.3 In the interests of minimising the number of statutory instruments required to transpose the Directive, the Instrument includes provision in policy areas on which the Department of Health and Social Care and the Ministry for Housing, Communities and Local Government lead. The Department has worked closely with both departments and the devolved administrations to coordinate the transposition measures.
- 7.4 The new duties in regulations 4 and 5 of the Instrument are intended to complement the existing measures set out in the radioactive contaminated land regime¹³, and in particular to ensure that appropriate actions are taken to control exposure to ionising radiation in the unlikely event that land contaminated as a result of a past practice, past work activity¹⁴ or the after-effects of an emergency is identified in the United Kingdom. A new duty to ensure reference levels are set for such contaminated land is being created. Reference levels are a tool for optimising¹⁵ any protective measures implemented as part of a strategy to reduce exposure of members of the public to ionising radiation. The reference level is a single value which can be selected from a range of values to allow for flexibility in the way contaminated land is managed. This flexibility may be utilised in situations where appropriate protection can be provided without causing a disproportionate detriment or an excessive cost. There is also a new duty to ensure that information is provided to the public concerning exposure to radiation from radioactive contaminated land. These duties are imposed on the “appropriate minister”, meaning the Scottish Ministers, the Welsh Ministers or a Northern Ireland department as relevant, depending on where the land is situated (and in so far as the relevant function is exercisable within devolved competence), or the Secretary of State. Information will be made available in the area the contamination

¹³ The radioactive contaminated land regime is a statutory regime setting out the UK’s approach to dealing with radioactive contaminated land.

¹⁴ An example of a past practice or past work activity is using radium, which is radioactive, to luminise aircraft instruments or watch dials. At the end of an aircraft’s life, it may have been disassembled in an aircraft breaking yard which would contaminate the ground with radium.

¹⁵“Optimisation” is explained in the Directive as “radiation protection of individuals subject to radiation exposure in public or in the workplace shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable, taking into account the current state of technical knowledge and economic and societal factors”.

exists and should follow consultation with expert bodies as necessary and appropriate, including with Public Health England and the relevant environment agency.

- 7.5 The regulations allow for flexibility in the way contaminated land is managed by creating a new requirement on the relevant minister (in so far as the function is exercisable within devolved competence), or the Secretary of State (in relation to England, or where the function is reserved) to ensure that appropriate arrangements are in place before the resumption of habitation and other activities on land which has been contaminated as a result of a past practice, past work activity or the after-effects of an emergency. This requirement reflects current best practice based on updated scientific methodologies and lessons learned from past experience.
- 7.6 Regulation 6 puts into place measures to reinforce the United Kingdom's existing administrative arrangements to deal with contaminated commodities and building material which is found to have already been incorporated into buildings. In the context of the Directive, contaminated commodities are commodities that are retrospectively found to be contaminated in a way that could pose a risk to public health if not properly managed. Building material can contain naturally occurring radionuclides which could lead to exposure indoors. No building material of concern has been identified in the United Kingdom to date, and there is a low chance such material will be identified in the United Kingdom in the future. To continue to strengthen the arrangements that protect against such commodities and material, there are new duties on the relevant minister for the part of the United Kingdom where the commodities or materials are situated (in so far as the function is exercisable within devolved competence), or the Secretary of State (in relation to England, or where the function is reserved) to ensure that, where there is evidence of an exposure from a contaminated commodity or building material incorporated into buildings that cannot be disregarded from a radiation protection point of view, strategies are put in place to manage the risks identified appropriately.
- 7.7 There are additional new duties in regulation 7 that deal with building material of concern from a radiation protection point of view, before it is used for construction. In the unlikely event that such material is identified in the United Kingdom in the future, there are several existing statutory regimes through which appropriate steps could be taken, such as building regulations. The Secretary of State must ensure that the activity concentrations are assessed, and if the material is liable to give gamma radiation doses exceeding a certain threshold, the Scottish Ministers, Welsh Ministers, a Northern Ireland department and the Secretary of State must each exercise their functions to ensure that such measures are taken as they each consider appropriate for the protection of members of the public, which may include imposing specific requirements in relevant building codes or restrictions on the use of such material.
- 7.8 The United Kingdom has in place robust safety, security and environmental protection regimes that comply with frameworks laid down at the EU and international levels. Given the strength of these regimes, the Department considers that the likelihood of any of the scenarios discussed above occurring is very small.
- 7.9 Regulations 8 to 12 put in place measures to deal with radon, which is a radioactive gas emitted from rocks and soil throughout the United Kingdom and can be damaging to health. The United Kingdom government has long recognised the health risks of radon and is committed to reducing its risk. Current practices that reduce public exposure to radon gas, such as the dissemination of information on its health risks, how to measure it and how to reduce its indoor concentration, are already well

established in the United Kingdom through administrative arrangements; this Instrument introduces new duties that make these practices a statutory requirement, reinforcing the United Kingdom government's commitment to maintaining the highest level of safety standards. There is a new duty on the Secretary of State to set reference levels for public exposure to indoor radon concentrations; a new duty to publish information on the health risks of radon; a new duty to publish and maintain a United Kingdom Radon Action Plan and a new duty to identify areas where high radon concentration in buildings is more likely. There is also a new duty on the Scottish Ministers, Welsh Ministers, a Northern Ireland department and the Secretary of State to put in place appropriate measures to prevent radon ingress into new buildings.

- 7.10 Regulations 13 and 14 put in place measures to deal with orphan sources. An orphan source is a radioactive source which should be under regulatory control but is not, for example because it has been abandoned, lost, misplaced or stolen. Orphan sources pose a risk to human health and the United Kingdom government is committed to reducing this risk. The United Kingdom's approach to orphan sources is already well established through administrative arrangements and these new measures are intended to strengthen the existing procedures by requiring the Scottish Ministers, Welsh Ministers, a Northern Ireland department and the Secretary of State to each exercise their functions to raise awareness about and issue guidance on dealing with orphan sources. New provisions on action to recover orphan sources left behind from past practices are intended to ensure that they come back under regulatory control and cease to be a risk to human health.

8. Consultation outcome

- 8.1 The Department conducted a United Kingdom wide public consultation from 5 October to 15 November 2017 (6 weeks) which invited views on all of the Department's policy proposals on public exposures and justification. The consultation also asked 12 substantive questions, of which one focussed on reference levels. An event was also held where professional bodies, industry associations, private and public sector organisations were invited to hear presentations on the Department's policy proposals and raise any concerns.
- 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 United Kingdom. Thirty-four respondents answered the question on reference levels; 88% of respondents were supportive of the proposals on reference levels and the remaining 12% were neutral.
- 8.3 Comments were made on the difference in approach between establishing reference levels in different regulatory regimes. This will be addressed through a guidance document on reference levels to be published by Public Health England in due course. Further comments were made on the difference between the recommended reference level for radon in a dwelling in the Instrument, compared to the World Health Organisation's recommended reference level. The reference level for radon in the United Kingdom will not be changed as it has been in place for many years and is in line with the requirements of the Directive. A final concern was raised on existing exposures following an emergency. The government position on reference levels as they apply during emergencies will be set out in the government response to the consultation on "Revised requirements for radiological protection: emergency preparedness and response". This will be published in due course.

- 8.4 The full government response to the consultation can be found at <https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-regulation-of-public-exposures-and-the-justification-of-practices>.

9. Guidance

- 9.1 A guidance document for the United Kingdom is being prepared by Public Health England to summarise the reference levels that are applicable to different exposure situations relevant to the Directive. The document will contain guidance for local authorities and other decision makers on the establishment and use of reference levels for existing exposure situations including contaminated land, incorporated building materials and contaminated commodities. The revised Statutory Guidance for Radioactive Contaminated Land¹⁶ will also contain further information about the relevant reference levels for land which has been contaminated as a result of past practice or work activity and how reference levels may be set for land which is designated as radioactive contaminated land and has been contaminated as a result of an emergency.
- 9.2 A Radon Action Plan (“the Plan”) is being prepared by Public Health England with input from a number of departments, agencies and other bodies to address the health risks from indoor exposure to radon. The Plan will describe the national radon strategy and will be published on gov.uk. The Plan will describe arrangements for managing exposure to radon in homes and workplaces, including arrangements and approaches used to communicate information and guidance on radon to relevant groups such as members of the public and local authorities.

10. Impact

- 10.1 There is no impact on business, charities or voluntary bodies.
- 10.2 The impact on the public sector was deemed to be negligible so was not considered for the final analysis of impacts.
- 10.3 An Impact Assessment (IA) is not attached to this memorandum as the measures of all legislative changes required to transpose the public exposures aspects of the Directive have a net direct impact on business or civil society organisations of less than £5 million annually. This qualifies for a fast track process, which does not require an IA for better regulation purposes.

11. Regulating small business

- 11.1 The legislation does not apply to activities that are undertaken by small businesses.

12. Monitoring & review

- 12.1 The likelihood of duties in regulations 4-7 and 14 of the Instrument being triggered is considered to be very low due to the strength of the United Kingdom’s existing safety, security and environmental protection regimes. In the event that the duties are triggered, the outcome will be subject to internal review by the Secretary of State in

¹⁶ S.I. 2018/ 429 amended the Radioactive Contaminated Land (Enabling Powers) (England) Regulations 2005 (S.I. 2005/3467) and the Radioactive Contaminated Land (Modification of Enactments) (England) Regulations 2006 (S.I. 2006/1379) in order to transpose certain requirements in the Directive. The Department is revising its Radioactive Contaminated Land Statutory Guidance in England, which will be laid in draft before Parliament in due course.

relation to England and the relevant minister in the devolved administrations, reporting on the extent to which the objectives of the duties have been achieved.

13. Contact

- 13.1 Alexander Hartley at the Department for Business, Energy and Industrial Strategy Telephone: 020 7215 1487 or email: Alexander.hartley@beis.gov.uk can answer any queries in relation to reference levels, radioactive contaminated land, contaminated commodities, building material and recovery of orphan sources. Trudy Netherwood at the Department for Health and Social Care Telephone: 020 7972 3255 or email: Trudy.netherwood@dh.gsi.gov.uk can answer any queries in relation to provisions on radon, provision of information on radioactive contaminated land and information on orphan sources.