

EXPLANATORY MEMORANDUM TO
THE ENVIRONMENTAL PERMITTING (ENGLAND AND WALES)
(AMENDMENT) (NO. 2) REGULATIONS 2018

2018 No. 428

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 Environmental Permitting (England and Wales) Regulations 2016 (S.I. 2016/1154) (“the 2016 Regulations”) to transpose the new requirements contained in the European Council Directive 2013/59/Euratom, 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. The Instrument also implements some additional measures to streamline and clarify existing legislation.

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 The Instrument is made principally to transpose new requirements set out in the Directive. The Directive consolidates 5 directives and a European Commission recommendation. In particular, it consolidates the Basic Safety Standards Directive (Council Directive 96/29/Euratom¹) (“the 1996 BSSD”) and the Directive on the control of high-activity sealed radioactive sources and orphan sources (Council Directive 2003/122/Euratom²) (“the HASS Directive”). The Directive also incorporates publications from the International Commission on Radiological Protection (ICRP), which were published in 2007³, and harmonises the Euratom regime with the International Basic Safety Standards issued by the International Atomic Energy Agency⁴. The deadline for transposition of the Directive is 6 February 2018.

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31996L0029&from=EN>

² <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0122&from=EN>

³ <http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103>

⁴ http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf

- 4.2 The Directive covers protection for workers, members of the public, and patients against the dangers arising from ionising radiation. Most of the requirements of the Directive are already implemented in existing UK legislation. This Instrument is necessary to transpose new requirements concerning public exposures that are not covered by existing UK legislation.
- 4.3 The 1996 BSSD and HASS Directive were transposed, so far as radioactive substances regulation⁵ is concerned, by the 2016 Regulations. The environmental permitting framework, originally created in 2007, provides a single streamlined environmental permitting and compliance regime in England and Wales. The regime regulates radioactive substances activities such as keeping and using radioactive material and accumulating and disposing of radioactive waste.
- 4.4 This instrument is part of a set of four which are being made by BEIS to transpose the public exposure and justification requirements of the Directive. The other instruments are:
- the Justification of Practices Involving Ionising Radiation (Amendment) Regulations 2018;⁶
 - the Radioactive Contaminated Land (Enabling Powers and Modification of Enactments) (England) (Amendment) Regulations 2018;⁷
 - the Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018.⁸
- 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 Instrument extends to England and Wales.
- 5.2 The Instrument applies to England and the sea adjacent to England out as far as the seaward boundary of the territorial sea, and to Wales.
- 5.3 It is subject to negative resolution procedure in both Houses of the UK Parliament and in the National Assembly for Wales.

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.

⁵ Radioactive substances regulation is the term commonly used to describe the different legislative regimes in place in different parts of the UK for pollution prevention and control (for England and Wales, the 2016 Regulations).

⁶ 2018/430

⁷ 2018/ 429

⁸ This instrument will be made on a separate date.

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 UK voted to leave the European Union. 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 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. The Euratom Community has established a set of basic safety standards to protect workers, members of the public, and patients against the dangers arising from ionising radiation. These standards also include emergency procedures that were strengthened following the Fukushima nuclear accident.⁹
- 7.3 Radioactive substances regulation in the UK is mostly in line with the requirements of the Directive. This Instrument implements new requirements of the Directive that relate only to “planned exposure situations”¹⁰ by amending the 2016 Regulations to bring them fully in line with the Directive. The changes to the 2016 Regulations required by the Directive are as follows:
- Dose coefficients: A dose coefficient is a dose per unit exposure to ionising radiation. The Directive requires the use of updated information on the use of dose coefficients and updated data for ionising radiation emitted outside the body (external exposure) for estimating effective and equivalent radiation doses to members of the public, which are found in the ICRP publications.
 - 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. The Directive extends the definition of an orphan source to include “unsealed sources”¹¹. There are also new requirements for the recovery, management, control and disposal of orphan sources.
 - High-activity sealed sources (“HASS”): The new definition of a HASS in the Directive is based on a single threshold of radioactivity, above which a source is categorised as a HASS. The requirement for users to report records on HASS annually has been removed from the Directive and the 2016 Regulations now set the appropriate interval for reporting at 5 years which will reduce burdens on the environment agencies and industry.
 - System of enforcement - inspections: The Directive updates the requirements for the inspection of radioactive substances activities. The environment agencies have an established, mature and robust system of inspection, so the Instrument makes statutory provision for practices already in place.

⁹ <https://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection>

¹⁰ A planned exposure situation is an exposure situation that arises from the planned operation of a radiation source or from a human activity so as to cause the exposure or potential exposure of people or the environment.

¹¹ An unsealed source is a source of ionising radiation in the form of radioactive material which is not encapsulated or otherwise contained.

- Clearance and exemption levels¹²: The Directive imposes a new set of values for the clearance and exemption of radioactive materials. In the 2016 Regulations, clearance and exemption are merged together into “out of scope” substances and “exempt” activities. Out of scope describes substances which are not considered to be radioactive for the purposes of regulation. If the substance is in scope, the activity may nonetheless be exempt from the requirement to hold a permit. The Instrument imposes the new values in both situations.
- Dilution: There is a new requirement to prohibit the deliberate dilution of radioactive materials for the purpose of removing them from regulatory control. Once amended by this Instrument, the 2016 Regulations will transpose this requirement for out of scope substances and for exempt activities.
- Radioactive waste from naturally occurring radioactive materials (NORM): NORM waste can be produced by industrial activities such as oil and gas production, titanium dioxide manufacture and china clay extraction. A new default clearance value for NORM has been introduced by the Directive, where radioactivity is incidental to the industrial activity.
- Geothermal energy production: The Directive requires that industrial sectors involving NORM are regulated. Geothermal energy production is the only NORM-producing industry in England and Wales that is not already captured in the 2016 Regulations.
- Monitoring and reporting radioactive discharges: The requirements imposed by the Directive, including in particular that operators of a nuclear power station or nuclear reprocessing plant must monitor and report radioactive discharges, are already complied with in the UK¹³. The Instrument makes statutory provision for practices already in place.
- Radioactive waste and radioactive waste advisers: The Directive imposes various requirements on operators to ensure members of the public are protected, including that operators consult a radiation protection expert. The Directive requires recognition arrangements to be in place for these experts. These requirements are all met throughout the UK in practice so the Instrument reflects current arrangements.

7.4 In addition, the Instrument amends the 2016 Regulations in order to streamline and clarify existing provisions and provide significant environmental benefits and savings for the private and public sectors. These measures will enable radioactive substances to continue to be used safely for nuclear power, healthcare and other beneficial applications. The key additional changes to the 2016 Regulations are:

- Requirement for map, plan or other description of the site: The Environment Agency has developed a new form of standard rules permit for multiple sites for operators who inadvertently receive radioactive materials or radioactive waste. The 2016 Regulations require a map, plan or other description of the site to be included in an environmental permit showing the geographical

¹² Clearance levels are activity concentration values at or below which materials arising from any practice subject to notification or authorisation may be released from regulatory control. Exemption levels are activity concentration values or total activity values at or below which a radiation source is not subject to notification or authorisation.

¹³ https://ec.europa.eu/energy/sites/ener/files/documents/2004_2_en.pdf

extent of the regulated facility. This requirement is not always appropriate in such cases, so this Instrument removes this requirement for standard rules permits covering specified radioactive substances activities at multiple sites.

- Gaseous Tritium Light Devices (GTLDs): GTLDs are convenient light sources where no power is available, and are in widespread use. An intact source up to a certain radioactivity level is exempt from the requirement for disposal as radioactive waste, so can be disposed with conventional waste to landfill. Widening the exemption to broken GTLDs will allow them to be disposed to landfill too.
- NORM waste exemption: The Instrument expands the definition of NORM waste by increasing the concentration values for certain types of NORM waste that can qualify for exemption, specifically for wastes containing lead-210+ or polonium-210. This change is expected to produce significant environmental and economic benefits associated with less generation and treatment of radioactive wastes.
- Legacy radium contamination: There are sites contaminated with radium as a result of historic activities such as radium luminising. These activities were either not regulated, or were regulated at lower standards than would be required today. The current out of scope value for radium-226 which has been processed for its radioactive properties is lower than background levels typically found in the UK. The Instrument applies a higher out of scope value for the remediation of such sites, to address the perceived need to remediate sites to below background levels.
- Gaseous radioactive waste arising from the production of oil and gas: The accumulation and disposal of NORM waste from the production of oil and gas currently requires a permit. In some cases the only radioactive substances activity taking place is the venting or flaring of trivial amounts of gaseous waste. Given the negligible radiological impact of these activities, an exemption has been created for them.
- Exemption for accumulating waste: The 2016 Regulations exempt specified sources from the requirement to hold an environmental permit. This Instrument adds a new provision disapplying the exemption for accumulating waste where the waste is or contains a HASS or source of a similar level of potential hazard, which will allow the environment agencies to enforce the requirements for security and financial provision if waste contains these sources.

Consolidation

- 7.5 The 2016 Regulations consolidated and replaced the Environmental Permitting (England and Wales) Regulations 2010. There are no plans to consolidate 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 2016 Regulations. The consultation asked 12 substantive questions, of which 7 focused on the proposed amendments to radioactive substances regulation. 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 UK. The majority of consultees supported the proposals. Below is an overview of the general responses from consultees on the proposed changes:

- In relation to the removal of the requirement for information about HASS to be reported on an annual basis, 57% of respondents agreed that annual reporting was unnecessary and the frequency of reporting should be reduced. Following consultation, it has decided that the appropriate interval for reporting is 5 years.
- 88% of people agreed with the proposed changes for NORM waste, as long as the changes do not impact on public safety. All landfill sites are required to follow the ALARP principle¹⁴, so the proposed changes do not increase public exposure.
- 84% of consultees agreed that geothermal energy production should be subject to radioactive substances regulation.
- 92% of respondents agreed that changes to reduce the regulatory burden for the remediation of sites contaminated with radium from legacy activities are proportionate. 36% of respondents thought “legacy” should not be defined by reference to a date, but by a description. It was agreed that, if a date were used, this should be the commencement date of the relevant legislation. Prior to the 1996 BSSD coming into force on 13 May 2000, activities involving radioactive substances were subject to less stringent regulation, so this is an appropriate date to use.
- 90% of respondents agreed that it would be proportionate to exempt accumulation and disposal of NORM wastes where flaring and venting are the only radioactive substances activity taking place in oil and gas production.

8.3 The full government response to the consultation can be found at the gov.uk website.

9. Guidance

9.1 Environment Agency guidance on environmental permitting was revised, simplified and streamlined under the Smarter Environmental Regulation Review (SERR) initiative, published on 1 February 2016.

9.2 There is an overarching Government Environmental Permitting Guidance document (the “Core Guidance”) which explains the environmental permitting system in detail.¹⁵ The Core Guidance is underpinned by additional guidance issued by Government and by the environment agencies on different aspects of the regime. There is a more detailed Government Environmental Permitting Guidance document helping readers understand the permitting and other requirements specific to the radioactive substances aspects of the Environmental Permitting Regulations.¹⁶

¹⁴ “As low as reasonably practicable” - this principle of radiation protection involves weighing a risk against the trouble, time and money needed to control it.

¹⁵ <https://www.gov.uk/government/publications/environmental-permitting-guidance-core-guidance--2>

¹⁶ <https://www.gov.uk/government/publications/radioactive-substance-regulations-rsr-guidance>

- 9.3 There are also other guidance documents. One is related to radioactive sources, helping the Environment Agency in performing its duties in relation to sources.¹⁷ A second is related to clearance and exemption, providing information to the environmental agencies and users on how the exemptions regime should be delivered.¹⁸

10. Impact

- 10.1 The final estimated Equivalent Annual Net Direct Costs to Business is -£4.6m (i.e. a £4.6m benefit). This is largely driven by the commensurate approach of the Directive allowing for permit holders to make cost saving measures, while maintaining the high standards of safety. The Net Present Value of these measures is £44m over a ten year period.
- 10.2 Charities and voluntary bodies are regulated in the same way as businesses and therefore the impact on these bodies is included in the above figure.
- 10.3 The impact on the public sector is on the Environment Agency in England, the Natural Resources Body for Wales, and local authorities. Since the Instrument amends provisions which already apply to those bodies, the impact is small as the costs incurred by those bodies are recovered through charges to permit holders as outlined in charging schemes approved by the Secretary of State or Welsh Ministers. They will need to reflect the updated regulatory requirements in the Directive although these are largely based on existing UK practice.
- 10.4 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 instrument applies to activities that are undertaken by small businesses.
- 11.2 The activities regulated by the 2016 Regulations include activities carried out by large and small businesses. It is not possible to exclude small businesses from regulation given that the purpose of the regime is protection of human health. However, the approach taken does provide exclusions and exemptions from permitting in specified cases. Environmental permitting is focussed upon reducing administrative burdens, and its risk-based approach allows the regulators to minimise burdens to all regulated businesses.
- 11.3 The consultation document was sent to businesses and business organisations, including those that represent small businesses.

12. Monitoring & review

- 12.1 A review clause was included with the 2016 Regulations in accordance with sections 28 to 32 of the Small Business Enterprise and Employment Act 2015 (c. 26). The review clause in the 2016 Regulations provides that the first report will be provided before the end of December 2019.

¹⁷ <https://www.gov.uk/government/publications/high-activity-sealed-radioactive-sources-and-orphan-sources-directive>

¹⁸ <https://www.gov.uk/government/publications/guidance-on-the-scope-of-and-exemptions-from-the-radioactive-substances-legislation-in-the-uk>

12.2 The environment agencies will provide information which will enable Government to monitor the effectiveness of these measures.

13. Contact

13.1 Edward Brierley at BEIS Telephone: 0300 068 6715 or email: edward.brierley@beis.gov.uk can answer any queries regarding the Instrument.