

EXPLANATORY MEMORANDUM TO
THE ENVIRONMENTAL PERMITTING (ENGLAND AND WALES)
(AMENDMENT) REGULATIONS 2011

2011 No. 2043

1. This explanatory memorandum has been prepared by the Department of Energy and Climate Change and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The draft Regulations amend some of the provisions relating to the regulation of radioactive substances in the Environmental Permitting (England and Wales) Regulations 2010 S.I. 2010/675 (“EP Regulations 2010”) in order to provide a more modern, transparent and user-friendly system for the regulation of radioactive substances which present a very low risk to people and the environment, while at the same time maintaining the necessary level of protection.

2.2 The draft Regulations achieve this by modifying the situations in which permits will be required, by amending what is defined as radioactive material or waste (and hence are subject to regulation) and by consolidating and revising the existing exemptions from the requirement to hold permits.

2.3 The draft Regulations also transpose provisions of the IPPC Directive (Directive 2008/1/EC) and the Water Framework Directive (Directive 2000/60/EC) that have been inserted by the Carbon Capture and Storage Directive (Directive 2009/31/EC) (“CCS Directive”).

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Regulations implementing Articles 32 and 37 of the CCS Directive will come into force on the day after the day on which the regulations are made. DECC considers that the short time period is justifiable in this case, in order that the draft Regulations can be brought into force as soon after the transposition deadline for the Directive as possible and in light of the high level of awareness of the proposed change among those affected. The requirements of the Directive have been in the public domain for some time and have been publicly consulted on (see section 8). There is a small number of highly specialised operators engaged in or planning to engage in carbon capture and storage activities in the UK.

4. Legislative Context

4.1 These draft Regulations are the final stage in amending the regulatory framework following a UK-wide review of the regulation of radioactive substances. The primary aim of the regulatory regime is to license the use and disposal of radioactive substances such that the public and the environment are protected from the effects of ionising radiation.

4.2 The initial stage of the review extended to England and Wales, and involved changing the procedure of licensing to the common environmental permitting system by migrating the substantive provisions of the Radioactive Substances Act 1993 (“RSA 1993”) into the EP Regulations 2010. This meant that the users of radioactive substances could benefit from the streamlined and less-burdensome common environmental permitting system.

4.3 This second stage involves more substantive changes to the regulatory regime. After a review, it has been decided to clarify and alter the scope of the regulatory system by amending the definitions of radioactive material and radioactive waste. Further, there are at present exemptions from the requirement for permits which are contained in 18 different statutory instruments. These orders are revoked by the draft Regulations, and new, more transparent and user-friendly exemption provisions are inserted in the EP Regulations 2010. In Scotland and Northern Ireland, equivalent changes will be achieved by amending RSA 1993 and by replacing the existing exemption orders with a single order.

4.4 The final remaining substantive provisions of RSA 1993 will be repealed and re-enacted by the draft Regulations. Because the changes to Schedule 23 of the EP Regulations 2010 are substantial, that Schedule is consolidated by the draft Regulations (as was requested by consultees).

4.5 The draft Regulations demonstrate clearer compliance with the Euratom Basic Safety Standards Directive (96/29/Euratom) (BSS Directive), which provides for a system of protection for workers and the public from the dangers of ionising radiation. Further, the consolidation of Schedule 23 of the EP Regulations 2010 by the draft Regulations re-transposes parts of that directive, and of the directive on the control of high-activity sealed radioactive sources and orphan sources (2003/122/EURATOM). Details of the re-transposition can be found in Annex A.

4.6 The draft Regulations also transpose Articles 32 and 37 of the CCS Directive which make amendments to the IPPC Directive and the Water Framework Directive. Both the IPPC Directive and the Water Framework Directive are transposed by the EP Regulations 2010. The remaining provisions of the CCS Directive will be transposed in other legislation where necessary.

5. Territorial Extent and Application

This instrument applies to England and Wales, including the sea to the edge of territorial waters.

6. European Convention on Human Rights

The Minister of State, Charles Hendry has made the following statement regarding Human Rights:

In my view the provisions of the draft Environmental Permitting (England and Wales) Regulations (Amendment) 2011 are compatible with the Convention rights.

7. Policy background

7.1 The first piece of legislation to regulate radioactive substances was the Radioactive Substances Act 1960 which did not come into effect until 1963, due to a number of anomalies, difficulties and instances of impractical regulation which were identified. These issues were addressed by a series of exemption orders which were introduced in a rather ad hoc way over time, without any underlying structure or philosophy. They were the mechanism for providing a degree of control, without excessive bureaucracy, over minor uses of radioactive substances where there was a clear benefit from use, whilst ensuring continued protection of the public and the environment. RSA 1993 was an amalgamation of the 1960 Act and parts of the Environment Protection Act 1990 and did not substantially change the structure of regulation.

7.2 The move in 2010 to the EP Regulations 2010 changed the mechanical process of regulation, but Government was not in a position at that point to alter the substantive detail of the system (including the 18 exemption orders), because of delay caused to that part of review by its highly technical nature.

7.3 Radioactive waste is a devolved matter, Scotland and Northern Ireland have chosen to retain RSA 1993, although they have agreed the need for modernisation in terms of the scope of regulation and the exemptions. This second stage review was therefore undertaken across the UK and involved extensive involvement of industry and regulators. The aim of the review was to provide a consistent UK-wide approach to the regulation of radioactive substances despite the use of different legislative vehicles.

7.4 The main effect of the draft Regulations will be to change the boundaries that define whether a particular substance is either outside the scope of legislation, capable of being exempt from full regulation or otherwise subject to permitting. This has been done for 3 main reasons:

(i) The current boundaries are in the wrong place. Whilst the current boundaries are based in part on risk, many of the demarcations appear to be arbitrary, contradictory across different exemption orders, or are based on risk assessments which are no longer available to us. Based on a consideration of risk, the boundaries have been redrawn and made substantially clearer.

(ii) The exact position of the boundary is currently vague in a number of circumstances. It can be difficult and time-consuming in some cases to work out on which side of a boundary to place certain materials and wastes (both for users and for the regulator who is often consulted due to the ambiguity). The new regime clears up a substantial number of these difficult areas.

(iii) There are gaps in the boundaries because the current exemption orders are up to 50 years old, and technology in this field continually advances. This means that situations which are proven to be of low risk are not exempted under the current legislation. The new regime has filled in a substantial number of these gaps to provide users and waste managers with a continuous set of boundaries.

7.5 The draft Regulations meet modern requirements in relation to practicality, durability, legal robustness, and a proportionate (i.e. risk-informed) regulatory burden on stakeholders. They also enable the UK to demonstrate clearer compliance with the BSS Directive and allow Government to respond to many stakeholders who believe the need to clarify and modernise the system is long overdue. Without a change to the exemptions regime there would be decreased confidence by users of the regulatory process.

7.6 The draft Regulations also transpose two Articles of the CCS Directive that impact on the permitting framework. Regulation 12 inserts a new regulated activity into Schedule 1 (activities, installations and mobile plant) of the EP Regulations 2010 relating to the capture of carbon dioxide; regulation 14 inserts a new activity for which the regulator is able to grant a permit into Schedule 22 (groundwater activities) of the EP Regulations 2010, in relation to the geological injection of carbon dioxide.

8. Consultation outcome

8.1 There has been substantial engagement with stakeholders during the development of the Regulations. Government has listened to the views of experts, industry, hospitals, universities and regulators throughout this process in workshops, by consultation and face-to-face meetings.

8.2 The overall architecture of the exemption regime was developed with input obtained at the very start of the programme during workshops with the non-nuclear industry, nuclear industry, interested groups and individuals. Subsequent events helped to clarify and discuss technical details of both draft Regulations and guidance.

8.3 Public consultation on the draft Regulations took place in 2009 and was supported by workshops to help explain the proposals and to receive feedback. There were 50 responses to the consultation which led to substantial alterations to the technical detail underpinning the new regime. In view of this, Government held a further round of stakeholder engagement in 2010 (50 responses received) and this led to the regime being refined to what is now contained in the draft Regulations.

8.4 The changes made in the Regulations have received universal acceptance by stakeholders. They have welcomed the clear risk-informed approach to categorising materials and wastes; the reduction in ambiguity and conflict between different exemption orders as they exist now, and they have particularly welcomed the approach which not only fills in the gaps in the boundaries as perceived today, but attempts to future proof the legislation. More detailed analysis of the consultations can be found at http://www.decc.gov.uk/assets/decc/Consultations/Consultation%20-%20future%20exemptions%20regime%20-%20RSA%201993%20and%20EPR%202010/1_20091203170342_e_@@_exemptionsconsultationsummary.pdf and <http://www.decc.gov.uk/publications/basket.aspx?FilePath=What+we+do%2fUK+energy+supply%2fEnergy+mix%2fNuclear%2f1810-future-exemptions-regime-revised-props.pdf&filetype=4&minwidth=true#basket>

8.5 A consultation seeking views on the CCS proposals described in paragraph 7.6 above ran from 3 September to 26 November 2010 and 24 respondents replied. The consultation document can be found at <http://archive.defra.gov.uk/corporate/consult/env->

[permitting-regs2010/index.htm](#). There were no objections or substantive comments on the proposals.

9. Guidance

9.1 There is one overarching guidance document (the Core Guidance) which provides advice on the EP Regulations 2010 and compliance with them, underpinned by separate Government guidance on each regime within the permitting framework.

9.2 Government will be issuing guidance to set out the intent of the legislation, primarily aimed at the regulator, the Environment Agency (“EA”). The EA will also be issuing regulators’ guidance, which will give users more detail on the way in which EA will implement the regulations. The guidance will be published prior to the new regime coming into force.

10. Impact

10.1 The impact on business, charities or voluntary bodies is to simplify the often complex system for users of radioactive substances that present very low risk to people or the environment.

10.2 The impact on the public sector is to simplify the often complex system for users of radioactive substances that present very low risk to people or the environment.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

10.4 No Impact Assessment is required for the amendments transposing the two Articles of the CCS Directive as it has been agreed with the Better Regulation Executive that there are no impacts on the UK economy by effecting these changes.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 To minimise the impact of the requirements on firms employing up to 20 people, the approach taken has focussed on risk-informed exemption provisions. It is not possible to simply exclude small firms from regulation, because of our obligations to transpose the BSS Directive.

11.3 The basis for the final decision on what action to take to assist small business was the guiding principles of the review itself, to reduce the regulatory burden on those users of radioactive substances which present a very low risk to people and the environment. This is a de-regulatory measure and by reducing administrative burdens its benefits will be greatest for small businesses who have less time to spend on administration.

12. Monitoring & review

12.1 A post implementation review of the EP Regulations 2010 is to be undertaken in 2015. The amendments made by these draft Regulations will be reviewed as part of that process.

12.2 The success criteria outlined at the start of the project will be used for the review. That is:

- Clarity of language and ease of use;
- Legal robustness;
- Comprehensiveness - dealing with all current and foreseen eventualities;
- Proportionality - the regulatory burden is risk-informed;
- The overall burden of regulation is reduced; and
- Businesses perceive that the exemption regime has been improved.

12.3 Government across the UK will be keeping regular contact with the environmental regulators and will be periodically seeking feedback from key stakeholders. The Post Implementation Review Plan can be found at Annex 1 of the Impact Assessment.

13. Contact

Steve Chandler at the Department of Energy and Climate Change Tel: 0300 068 6104 or email: steve.chandler@decc.gsi.gov.uk can answer any queries regarding the instrument.

Annex A: Transposition tables

The tables below show how the Environmental Permitting (England and Wales) Regulations 2010 (S.I. 2010/675), as amended, now transpose the relevant parts of the Basic Safety Standards Directive, the HASS Directive and the CCS Directive. References to a provision in regulations are therefore references to provisions in those regulations rather than to the draft Environmental Permitting (England and Wales) (amendment) Regulations 2011.

The Basic Safety Standards Directive (Directive 1996/29/EURATOM)

Directive article	Objective	Regulations provision
3(1)	Requiring the reporting of certain practices involving radiation	Regulations 7, 8, 12(1)(a) and paragraphs 3-6 and 11 of Part 2 of Schedule 23
3(2) and Annex 1	Exempting certain practices from reporting	Part 7 of Schedule 23
4(1)/(2)	Requiring the authorisation of certain practices involving radiation	Regulations 7, 8, 12(1)(a) and paragraph 3-6 and 11 of Part 2 of Schedule 23
4(2)	Exempting certain practices from the requirement for authorisation	Part 7 of Schedule 23
5(1)	Authorisation and clearance for disposal, recycling or reuse of radioactive material	Regulations 7, 8, 12(1)(a) and paragraphs 3-6 and 11 of Part 2 of Schedule 23
5(2)	Exempting certain operations covered in article 5(1) from the requirement for authorisation	Sections 5-8 of Part 7 of Schedule 23
6(3)	Setting the general principle of 'optimisation'	Paragraph 1 of Part 4 of Schedule 23
7	Obligation to use dose constraints for protecting the public from radiation	Paragraph 2(1) of Part 4 of Schedule 23
13	Setting dose limits for members of the public	Paragraph 1(b) of Part 4 of Schedule 23
14	Requiring the exposure of the population as a whole to radiation to be as low as reasonably achievable	Paragraph 1(a) of Part 4 of Schedule 23
15, 16	Methodology for the estimation of the effective dose	Paragraph 2(2) of Part 4 of Schedule 23
40(3), 41	Obligation to apply radiation protection in relation to work activities involving natural radiation	Regulations 7, 8, 12(1)(a) and paragraph 2-4 and 11 of Part 2 of Schedule 23
45	Sets out requirements for the estimation of population exposure doses	Paragraph 2(2) of Part 4 of Schedule 23
47	Requires member states to ensure that certain requirements in relation to health and environmental protection are fulfilled	Paragraph 2(2) of Part 4 of Schedule 23
53	Requires a system to be in place for intervening in the case of potential lasting exposure; including the after-effects of a former practice	Paragraphs 3 and 4 of Part 4 of Schedule 23

European scrutiny: DECC does not hold scrutiny details in relation to this directive.

**The HASS Directive
(Directive 2003/122/EURATOM)**

Directive article	Objective	Regulations provision
Article 1(2)	To exclude certain sources from the scope of the Directive.	Schedule 23, Part 5, paragraph 1
Article 2(a), (b)	To define expressions used in the Directive.	Schedule 23, Part 5, paragraph 1
Article 3(1)	To ensure that holders of HASS have appropriate authorisation.	Regulations 7, 8, 12(1)(a), and paragraphs 3, 4, 5, 6 and 11 of Part 2 of Schedule 23
Article 3(2) and (3)	To ensure that before issuing authorisation adequate arrangements have been made for the safe management of HASS and to ensure that the authorisation covers certain minimum requirements.	Schedule 23, Part 5, paragraph 5(1)(a)
Article 4	Member States to set up a system to enable them to be adequately informed of individual transfers of sources.	Schedule 23, Part 5, paragraph 5(1)(b)
Article 5(1) and (2)	To ensure that the holder is required to keep records of HASS, their location and any transfers and provide them to the competent authority, updated as necessary.	Schedule 23, Part 5, paragraph 5(1)(c)
Article 5(3) and (4)	The competent authority to keep and update as necessary records of authorised holders and the sources they hold.	Schedule 23, Part 5, paragraph 6(a)(i)
Article 6	To ensure that the holder carries out suitable tests; periodically verifies the location and condition of HASS; has documented security measures; disposes of disused HASS promptly; checks the status of recipients of transferred HASS; and notifies the competent authority of loss, theft, or unauthorised use of a HASS and any unplanned exposure of workers or public.	Schedule 23, Part 5, paragraph 5 (1)(d)
Article 7	To ensure that the manufacturer or supplier identifies each source by a unique number and provides written information and photographs relating to the design type.	Schedule 23, Part 5, paragraph 5(1)(e)
Article 8	To ensure that staff training and information covers safe management of sources and possible consequences of loss of control.	Schedule 23, Part 5, paragraph 7
Article 9(1)	Competent authorities to have arrangements in place to deal with orphan source incidents.	Schedule 23, Part 5, paragraph 8(1)
Article 9 (2)	Member States to ensure technical advice and assistance is promptly available in suspected orphan source incidents.	Schedule 23, Part 5, paragraph 4
Article 10	Member States to ensure a system is in place to fund the recovery of orphan sources.	Schedule 23, Part 5, paragraph 8(2)
Article 12	Member States to establish a system of inspections.	Schedule 23, Part 5, paragraph 6 (b)
Article 13(1)	Member states to designate competent authority to carry out tasks in accordance with the directive	Regulation 32
Article 15	Member States to determine penalties, which are to be effective, proportionate and dissuasive.	Regulation 39
Article 16(1)	To make provision in relation to HASS placed on the market before 31/12/05 concerning information and hazard marking requirements	Schedule 23, Part 5, paragraph 5(2)

European scrutiny: DECC does not hold scrutiny details in relation to this directive.

**The CCS Directive
(Directive 2009/31/EC)**

Directive article	Objective	Regulations provision
Article 32	Amends Directive 2000/60/EC (the Water Framework Directive) by adding to the list of exceptions from the prohibition of direct discharges of pollutants into groundwater. The amendment adds to those exceptions the injection of carbon dioxide streams into geological formations which for natural reasons are permanently unsuitable for other purposes.	Paragraph 8 of Schedule 22 to the EP Regulations 2010 The Environmental Permitting (England and Wales) Regulations 2010
Article 37	Amends the Integrated Pollution Prevention and Control Directive (2008/1/EC). The IPPC Directive applies to certain industrial activities listed in its Annex I and Article 37 extends that list to include the capture of carbon dioxide streams from installations already covered by the Directive.	Part 2 of Schedule 1 to The Environmental Permitting (England and Wales) Regulations 2010

European scrutiny: EM 5835/08 of 23 January 2008 was considered in (Commons) European Scrutiny Committee on 5 March 2008 and referred for debate in Europe Committee. The Commons cleared the EM on 2 June 2008. The EM was cleared by the Lords on 19 November 2008 after referral to sub-committee and requests for further information.