EXPLANATORY MEMORANDUM TO

THE ENVIRONMENTAL PERMITTING (ENGLAND AND WALES) (AMENDMENT) REGULATIONS

2011 No. [DRAFT]

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.

Title:	Impact Assessment (IA)
Lead department or agency:	**IA No:**
	Date: 01/01/2010
Other departments or agencies:	**Stage:** Final
	Source of intervention: Domestic
	Type of measure: Secondary legislation
	Contact for enquiries:

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Maximum of 8 lines

What are the policy objectives and the intended effects?

Maximum of 8 lines

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Maximum of 10 lines

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Month/2012 **What is the basis for this review?** PIR. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:  Date: ----------

Summary: Analysis and Evidence

Policy Option 1

Description:

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

Maximum of 5 lines

Other key non-monetised costs by 'main affected groups'

Maximum of 5 lines

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

Maximum of 5 lines

Other key non-monetised benefits by 'main affected groups'

Maximum of 5 lines

Key assumptions/sensitivities/risks **Discount rate (%)**

Maximum of 8 lines

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes	OUT

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			01/01/2010		
Which organisation(s) will enforce the policy?					
What is the annual change in enforcement cost (£m)?					
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**		**Non-traded:**
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**		**Benefits:**
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	
Small firms Small Firms Impact Test guidance	No	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

No.	Legislation or publication
1	***Ref 1.*** 2009 Public Consultation package (including consultation document, impact assessment and references 2 to 7 below)
2	***Ref 2***. Exemption Order Review: Expert Group Elicitation Workshop Report, 11 July 2007 (Appendix 5)
3	***Ref 3***. Summary note of Expert Group Workshop on Options Assessment in Reading, 30 January 2008 (Appendix 6)
4	***Ref 4***. Informal consultation on suggested Exemption Order Framework 25 August 2008 (Appendix 7)
5	***Ref 5***. Schedule 1 of RSA93 – expert group recommendations (date?) (Appendix 9)
6	***Ref 6***. Summary note of Framework Workshop in Edinburgh, 30 January 2009 (Appendix 8)
7	***Ref 7***. Proposals for A Future Exemptions Regime under The Radioactive Substances Act 1993 and The Environmental Permitting Regulations 2010: Consultation Summary document, 4 December 2009
8	***Ref 8***. 2010 stakeholder engagement package (including engagement document and revised impact assessment)
9	***Ref 9***. Full list of EOs on the DECC website
10	***Ref 10***. RSA93
11	***Ref 11***. EPR10
12	***Ref 12***. BSSD
13	***Ref 13***. UK Government's Low Level Radioactive Waste Policy 2007

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs										
Annual recurring cost										
Total annual costs										
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base (for summary sheets)

1. Introduction

1.1 The Radioactive Substances Act 1993 (RSA93) provides a prior permitting regime for the registration of premises keeping and using radioactive material, and for the authorisation of the accumulation and disposal of radioactive waste. Responsibility for the subject matter of the RSA93 lies with the administrations in England, Scotland, Wales and Northern Ireland, and it is administered by the Environment Agency in England and Wales, Scottish Environmental Protection Agency, and Northern Ireland Environment Agency (referred to as the "environmental regulators" throughout the rest of this document) leading to a consistent UK-wide approach to the regulation of radioactive substances.

1.2 A review of the exemptions regime (what falls in or out of the scope of the legislation and what does not need prior permitting) has resulted in proposals that, when implemented, will significantly update the 50 year old regulatory system in the UK. The proposed regulations will amend the definitions of radioactive materials and radioactive wastes resulting in a modern, transparent system for determining what radioactive substances are subject to the requirements of the RSA93. The exemptions regime will considerably simplify the often complex system for users of radioactive substances that present a very low risk to people or the environment.

1.3 There has been extensive stakeholder engagement during the development of these proposals including intergovernmental meetings, stakeholder workshops, meetings with targeted groups, presentations at domestic and international professional radiological working groups, and informal consultations and full public consultations. These have provided a transparent approach to the development of the regime and have received a favourable reception from stakeholders.

1.4 In 2009, RSA93 was repealed (with the exception of exemption order provisions which await the outcome of this review) and migrated into the Environmental Permitting Regulations 2010 (EPR) in England and Wales. The changes made by incorporating RSA93 into the Environmental Permitting regime are essentially procedural, to help deliver the same level of public and environmental protection more efficiently and in a less burdensome manner.

1.5 The outcome of the proposal under consideration in this impact assessment will therefore be incorporated directly into EPR in England and Wales. In Scotland, the scope of RSA93 has already been amended by regulations under the European Communities Act 1972 and the new exemption order has been made under RSA 93; it will come into force in October 2011. An identical mechanism will be used to amend legislation in Northern Ireland after the elections in May 2011, with an intention to also come into force in October 2011.

1.6 Although different legislative vehicles are being used across the UK to implement the new regime, the substantive content of the proposals are the same. For the purposes of this document we refer to both EPR and RSA 93 as RSA 93.

2. Purpose and intended effect

Objective

2.1 Government's better regulation agenda aims to simplify regulations, by reducing the regulatory burden on industry through improvements in regulation. The review, which is re-evaluating the scope of regulation and exemption from some of RSA 93 provisions, is being undertaken across the UK in conjunction with the Devolved Administrations. It will introduce new secondary legislation which meets modern requirements in relation to practicality, durability, legal robustness, and a proportionate (i.e. risk-informed) regulatory burden on stakeholders. It will also enable the UK to demonstrate clearer compliance with the EU Basic Safety Standards Directive (96/29/EURATOM) and will allow Government to respond to many stakeholders who believe the need to clarify and modernise the system is long overdue.

2.2 In short, the aim is to produce a simpler, less burdensome exemptions regime whilst at the same time maintaining the necessary protection for people and the environment.

Background

2.3 The intent of the RSA93 and its exemption orders is the protection of human health and the environment from risks associated with the disposal of radioactive waste. Schedule 1 of RSA93 sets concentration thresholds for naturally-occurring radioactivity below which the Act does not apply. The Act currently applies to all man-made radioactive substances no matter how low the concentration. EOs are the mechanism for providing a degree of control, without excessive bureaucracy, over minor uses of radioactive substances where there is a clear benefit from their use, whilst ensuring continued protection of the environment and the public.

2.4 The first Radioactive Substances Act 1960 (RSA 60) came into full force in 1963. Almost immediately, a number of anomalies, difficulties and instances of over-regulation were identified. These were addressed by a series of EOs which were introduced to meet the needs of specific circumstances and were not developed with any underlying structure or philosophy. Since then a series of EO's have been added to the regime, totalling 18 overall, which are listed at the references link on page 4 (***Ref 9***).

2.5 In essence very little has changed in terms of the legislation since the early 1960's. In contrast the international framework for controlling radioactive substances has moved on considerably. The local government, educational, health, etc. systems within the UK on which the EOs were based have also moved on significantly, rendering some of the content out-of-date and much of it very difficult to follow or apply to today's activities.

Rationale for Government Intervention

2.6 The regulatory landscape has changed since the Act was first introduced with greater emphasis on a graded or proportional approach to regulation and a desire to reduce the administrative burden on industry. The EOs are now out-dated subordinate legislation for reasons including:

- The language, which is archaic making them difficult to follow and interpret. The scientific units used in most EOs have been superseded by new units, as recommended by the International Commission on Radiological Protection and adopted in European legislation.

- The requirements of users which have changed over time, with some EOs assuming greater significance and others bearing little or no current relevance or importance.

- The many anomalies which need to be addressed. The EOs have been amended piecemeal over the years to clear up some anomalies or cater for new practices, but this has, in some cases, lead to a lack of transparency and difficulty of use. In addition , the last version of government guidance was issued in 1982 and is now almost irrelevant. Clear and comprehensive government guidance is therefore required.

2.7 Recent experience has shown that even minor changes to existing EOs is time and resource intensive. An example of this is the Testing Instruments Exemption Order which was amended in 2006. This work highlighted that even minor modifications to some paragraphs often have ramifications for other paragraphs, for other EOs, or even for the Act itself. This turned what should have been a simple review, into a complicated and protracted legal process.

2.8 A wholesale review of the exemptions regime is long overdue and opportunities were missed in 1993 when RSA was consolidated, and again in the late 1990s when the revised Basic Safety Standards Directive came into force (***Ref 12***). There has been widespread pressure from a number of constituencies, including operators, regulators, government departments and the radiation protection community for such a review. This was confirmed by way of an informal consultation carried out in late 2005, and by discussions at the governmental Radioactive Waste Policy Group in February 2006. By undertaking this review, new secondary legislation will be enacted throughout the UK which will use plain English, meet current and future requirements, be legally robust, comprehensive and reduce the regulatory burden in what is a technically complex area. Without a change to the exemptions regime there will be decreased confidence by users of the regulatory process.

2.9 The rationale for reviewing the current exemption orders regime is therefore threefold:

- reducing regulatory burdens under the UK Government's better regulation agenda;
- demonstrating clearer compliance with the EU Basic Safety Standards Directive (96/29/Euratom) (BSSD) which protects the health of workers and the public from the dangers of ionising radiation; and
- responding to stakeholder views that a review of exemption orders is long overdue.

3. Consultation

3.1 There has been substantial engagement with stakeholders during the development of the regulations. Government has listened to the views of stakeholders throughout this process in workshops, by consultation and face-to-face meetings. The overall architecture of the exemptions regime was developed with input obtained during workshops with the nuclear industry, small users from the non-nuclear industry and other interested groups or individuals.

3.2 Formal public consultation on the draft regulations took place in 2009 and was supported by workshops to help explain the proposals and to receive feedback. The outcome of the consultation led to fairly substantial alterations to the regime. While the principles upon which the regime was based remained relatively unaltered, the detail of how they were implemented underwent substantial change. In view of this Government held a further round of stakeholder engagement in 2010. More detail on the 2009 and 2010 stakeholder engagement can be found in the reference links on page 4 (***Ref 1*** and ***8***).

Within Government

3.3 The consultation took into account the recommendations of government departments and agencies across the UK, such as the Ministry of Defence; the Nuclear Decommissioning Authority; the Health and Safety Executive; the Department of Health; the Department for Business, Innovation and Skills; the Department for Education and the Environment Agency.

Public consultation

3.4 The formal consultation paper was designed to obtain the views of those who had a technical knowledge of the issues regarding the nature, use and disposal of radioactive substances as well as those, with both technical and non-technical knowledge, who used the current system. This included professional and academic associations, industrial institutions, international oversight bodies and non-governmental organisations.

Business

3.5 The consultation process took UK businesses into account. These businesses span both the nuclear and non-nuclear industry, including international energy companies, manufacturing companies, fire industry, research industry, agriculture, heavy mineral industry and supply chain companies to the energy sector to name a few. The financial implications of the regulations are also relevant to hospitals who use radioactive material in medical and veterinary treatment, and schools and universities who use radioactive material for teaching and research.

4. Options

4.1 Following a stakeholder engagement workshop in 2007 six options for the framework of the proposed exemptions regime were developed. These options underwent a thorough assessment which involved extensive engagement with experts from Government, the environmental regulators and persons currently holding permits under RSA93. The options considered were:

Option 1. Do nothing
- The regime would be left entirely as it is.

Option 2. Minor updates of existing Exemption Orders
- The regime would be largely left as it is, with minor linguistic and stylistic changes to the EOs.

Option 3. Full updates of existing EOs
- All eighteen EOs would be reappraised and updated.

Option 4. Rebrigading of EOs
- The EOs would be reappraised and simplified into fewer EOs.

Option 5. Top level EO rationalisation and simplification with all the detail in schedules
- All the EOs would be revoked and replaced by a single EO, with numerical values specific to substances and practices contained in the schedules.

Option 6. Goal setting/ dose based approach
- All the EOs would be revoked and the dose, rather than the substance or the practice, would be regulated.

4.2 A workshop was held to test the inputs to the proposed new framework and the general principles were accepted by stakeholders. This workshop considered all 6 options against five agreed attributes and their conclusions are summarised in Table 1 on the following page.

4.3 Following the option assessment process detailed work was undertaken to populate the preferred framework (Option 5) with numerical values and conditions.

4.4 It was during the course of this detailed work to develop a new exemptions regime, that it became apparent that, in addition to the exemption orders, attention to the scope of RSA93 itself was important in order to provide a comprehensive and logical regime. This aspect was therefore added to Option 5, which essentially became a top level rationalisation and simplification of the existing regime. A consultation stakeholder workshop was held in July 2009 in parallel with a full public consultation exercise from June to September 2009 and a further round of stakeholder engagement was undertaken in 2010. A more detailed look at the options process and development of the preferred option, with details of how it simplifies the existing regime, can be found at **Annex 2**.

4.5 In view of the extensive engagement used in the selection and development of the preferred option (5), it is only considered appropriate to consider the two broad options in this assessment:

– Do nothing (baseline)

– Preferred option (top level rationalisation and simplification of the existing regime)

Table 1

Attributes	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Compatibility with other policy/ regulatory initiatives	Least Compatible	Not Better Regulation	Potential conflict with Euratom	Likely to produce simplification and easier to update	Most compatible with Better Regulation and other environment legislation	Increases regulatory burden on user and regulator
Adaptability to future scientific and technological developments	Difficult to update and adapt	Difficult to update and adapt	Less easy to update and adapt than 4 and 5	Quicker to make changes as there would be fewer EOs	Very adaptable	Very Adaptable
Administrative or financial benefits	None	High cost for few benefits	No unique benefits	Same cost as 5 with fewer benefits	Significant up front expenditure, but sustainable ongoing savings	High cost and long time to wait for benefits, but would potentially drive innovation
Proportionate and risk informed	Neither	Neither	Proportionate	Proportionate and risk informed	Proportionate and risk informed	Proportionate and risk informed
Expected development time	Waste of time	Waste of time	Similar to 4 and 5	Similar to 3 and 5	Similar to 3 and 4	Short development time, but long implementation time

5. Analysis of Costs/Benefits

Proposed approach to analysis

5.1 Cost and benefit estimation for the option is not straight-forward for two reasons:

(i) We do not know exactly how many users of radioactive substances are currently employing the exemptions regime. This is because EOs are designed to reduce administrative burdens, and hence no reporting to a relevant authority is necessary. There are therefore no formal records of EO users in the UK. We have tried identifying users through extensive stakeholder engagement and the EA also commissioned a report looking at Current and Future Uses of Exemption Orders (EA, 2009); these have both assisted with identifying the breadth of use, but still have limited validity.

(ii) Stakeholders have found it difficult to quantify their costs and benefits in financial terms. We conducted an elicitation exercise in 2007, based on preliminary proposals, to ascertain the views of key stakeholders in various industry sectors on the costs and benefits of the proposals. This exercise was followed by a more formal request for cost and benefit information during the 2009 consultation. Although the responses were very encouraging ('we welcome these proposals and believe that they will have positive benefit to us in terms of ease of use…", etc.), and helped identify circumstances through which costs and benefits would arise from using the new regime, in general, respondents were unable to quantify the costs and benefits. This was also the case in the further 2010 stakeholder engagement exercise, although we have been able to elicit useful information to refine the methodology further as set out in paragraph 5.5 (ix) and **Annexes 2 and 3**.

5.2 Following the stakeholder engagement exercise in 2010,which did not provide specific time benefits data, we have worked with key experts who we believe are representative of the wider user pool. These covered extensive and non-extensive users, RPAs, as well as the environmental regulators from across the UK. We worked with them to refine the methodology and estimates used in this assessment following consultation to allow for the disparate uses of exemptions and incorporated sensitivity analysis to account for uncertainties in our assumptions. The main revisions include:

- Accounting for disparate use by splitting the user pool into extensive and non-extensive users.
- Refining the user and environmental regulator day costs to allow for industry biases.
- Incorporating costs for various industries to produce their own guidance.
- Refining the time costs and savings for the RPAs and environmental regulators to a more realistic range of values and incorporating agreed time costs and savings for industry users.

5.3 We believe that the main monetised costs and benefits of the preferred Option relative to 'do nothing' are limited to:

One-off transition costs:

- One-off transition cost of familiarisation with the new regime for existing EO users;
- One-off transition cost of familiarisation with the new regime for regulators;
- One-off transition cost of familiarisation with the new regime for Radiation Protection Advisors (RPAs);
- One-off cost for regulators producing procedural guidance for industry; and

- One-off cost for Industry producing internal procedural guidance.

  Recurring benefits:

- Recurring benefits for RPAs from reduced time spent using EOs demonstrating compliance;
- Recurring benefits for existing users from reduced time spent using EOs demonstrating compliance;
- Recurring benefits for new users from reduced costs of familiarisation; and
- Recurring benefits to regulators for reduced time dealing with calls for advice about the exemptions regime

5.4 Confirmation of the methodology, assumptions and values (including ranges for input time and rate costs) was received at a meeting of experts from industry and environmental regulators (DECC, December 2010) (See Annex 3). General agreement was reached that the estimates of costs and benefits to each stakeholder group were prudent and reflect a realistic assessment of the requirements, on average, under the current and proposed new regimes. Due to the absence of a notification requirement, and therefore firm data on administrative burdens under the current arrangements, or on burdens from a yet to be introduced regime, the consensus reached on time savings (outlined in the assumptions section below) is considered the most robust method of monetising costs and benefits. This methodology has been used by administrations across the UK to assess the impact of the new regime.

Assumptions

5.5 The estimates set out in this impact assessment are based on assumptions, and have associated uncertainties. Due to the nature of the EO regime resulting in there being no official data on usage, the assumptions are in the main informed by consultation with stakeholders and experts in the area. It is assumed that all administrations across the UK will either retain or adopt a consistent regulatory framework, which will come into force at the same time, and currently scheduled for October 2011. The main assumptions are:

(i) **Total number of EO users**: The environmental regulators have estimated that there is a total user pool of 22,000 using the exemptions regime. This is derived from there being currently 3,850 permits issued across the UK and that, on average, a permit holder has 1.75 permits (thus the current number of permit holders is 2,200). They believe there are at least 10 EO users for every permit holder, giving the total user pool of 22,000.

(ii) **Annual entrants/exits from the EO regime**: It is estimated that around 1,100 new users per year would be required to use the exemptions regime. This is based on information presented by the environmental regulators that new applications account for around 5% of the 3,850 issued permits means 193 new permits per year. With an average of 1.75 permits per holder, this means 110 new organisations per year would enter the UK regulatory regime with an average of 10 EO users for every organisation this gives a total of 1,100 new users. The number of users exiting the regime is expected by the regulators to be broadly equivalent to the number of entrants and as a result it is assumed that the overall number of users over the appraisal period will remain constant at 22,000.

(iii) **Segregating EO users by level of use**: Due to differing usage of EOs by industry it has been necessary to provide an estimated segregation of the total user pool as follows: of the 22,000 users, 3,850 are categorised as extensive users, and 18,150 as non-extensive users. Within this breakdown (and assuming the same ratio), the 1,100 new entrants annually are estimated to comprise 192 extensive users and 908 non-extensive users (as existing users). These estimates are based on advice from stakeholders within the nuclear and non-nuclear industries and from the environmental regulators, e.g. Association of University Radiation Protection Officers, CLEAPSS (school representatives), UK Heavy Minerals and Sands

Association, Institute of Physics and Engineering in Medicine, Clearance and Exemption Working Group (nuclear industry).

(iv) **Cost of professional advice**: The Society of Radiological Protection (the UK organisation of professional radiation specialists) estimate that there are around 550 Radiological Protection Advisers (RPAs) in the UK and that the daily consultancy costs range from £500 to £1500 for non-nuclear and nuclear specialists respectively. The daily cost of professional advice required by a user is estimated at £750 based on advice from key stakeholders, including environmental regulators. It has been selected as an appropriate modal average figure as the majority of users are from the non-nuclear industry.

(v) **Cost of regulatory input**: Based on the advice from environmental regulators, their estimated daily cost for exemption related work is assumed at £900. The UK has around 60 regulators who currently spend on average 3% of their time dealing with EO matters. Regulators costs range from £700 per day for non-nuclear regulators to £1500 per day for nuclear regulators so an average of £900 per day has been selected as an appropriate figure (as most users are from the non-nuclear industry). This is based on advice from the environmental regulators.

(vi) **Cost of user time**: It is estimated that the average user cost is around £250/day (based on a range of £150 per day to £350 per day). These estimates are based on advice from stakeholders within the nuclear & non-nuclear industries.

(vii) **Permitting changes**: Although environmental regulators believe fewer permits will be required under the new regime, there will be a shift whereby some users will be permitted in the future who are not currently permitted, and vice versa. For the purposes of this impact assessment, it has been assumed that the number of permits will remain the same. This assumption will be considered as part of the PIR.

(viii) **Waste management costs**: Through discussions with environmental regulators and deliberations at workshops it is anticipated that waste management costs will decrease under the new exemptions regime. Although some users will have higher waste management costs (e.g. titanium dioxide producers, users of minerals/sands), others will see waste management costs decrease (e.g. nuclear industry, medical/veterinary practitioners), and hence for the purposes of this impact assessment, it is assumed that the overall waste management costs will not change. This assumption will be considered as part of the PIR.

(ix) **Cost and benefit time assumptions**: The estimated time costs and savings used in this impact assessment were arrived at through lengthy engagement with key experts from nuclear/non-nuclear industries and environmental regulators. Following review of the current proposals, a sample of responses from a variety of industries and from the environmental regulators who have extensive dealings with these industries, which are a good representation of the wider user pool, indicate that although there are uncertainties about the assumptions relating to time spent with the current and proposed regimes, the time estimates used are reasonable averages for extensive and non-extensive current and new users as well as for the RPAs and environmental regulators. As outlined in paragraph 5.1 (ii), while the engagement responses demonstrated a general consensus that the new regime would lead to time savings, the heterogeneous nature of the user groups and the lack of quantification in responses meant that it was not possible to directly identify a representative range. As a consequence, time savings had to be informed via consultation with industry experts and environmental regulators. Several examples, in a variety of contexts, of how such time savings will arise in practice are set out on page 26 in **Annex 2**.

(x) **Appraisal period**: The new regime will last for perpetuity but the NPV calculation is based on 10 years which is both prudent and in line with the Better Regulation Executive's guidance. All costs are transitional and incurred in 2011; the cost estimates are therefore not discounted. All benefits are on a recurring basis over the appraisal period 2011 - 2020.

Cost and benefits

Baseline - Do Nothing

5.6 If we do nothing, this would maintain the current situation where we have out of date legislation which is not proportionate or risk-informed and is over-burdensome to users without supporting guidance.

5.7 Costs and benefits of the new exemptions regime are estimated relative to a cost-neutral baseline; all stakeholder engagement exercises were undertaken with an assumption that all administrations throughout the UK would either retain the same regulatory system or adopt a common framework. In reality, with revised legislation very recently being laid in Scotland, and likely to be laid in Northern Ireland over the coming months, it is anticipated that there will be an additional burden to users that operate across the UK once legislation comes into force in these administrations. Due to the criticality of implementing these regulations within England and Wales, we have not had an opportunity to fully assess these anticipated costs, but have been contacted by stakeholders who have expressed nervousness at having inconsistent regulations throughout the UK.

The Preferred Option - Top Level Rationalisation and Simplification of Existing Regime

Option Summary

5.8 The revised exemptions regime replaces the present suite of 18 EOs with one set of exemption provisions and includes amendments to the definitions of radioactive material and radioactive waste which determines what material is outside the scope of legislation. Supporting guidance is also provided.

Costs

5.9 The main monetised costs highlighted in paragraph 5.3 are detailed below:

5.10 **Existing users – cost of familiarisation**: The one-off cost to existing users of familiarisation with the new regime is estimated to be £3.6 million. This is based on a combination of 3,658 extensive users, requiring 3 days for familiarisation at a cost of £250 per day giving a cost of £2.7 million; and 17,243 non-extensive users requiring 0.2 days for familiarisation at a cost of £250 per day giving a cost of £860,000. It should be noted that the time estimate provided for non-extensive users reflect an average and not all businesses will have a cost of familiarisation as they will be unaffected by the revised regime.

5.11 **RPAs – cost of familiarisation:** The one-off cost of familiarisation for RPAs is estimated at £2.06 million. This is based on 550 RPAs, requiring 5 days for familiarisation at a cost of £750 per day.

5.12 **Regulators – cost of familiarisation:** The one-off cost for regulators of familiarisation with the new regime is £162,000. This is based on 60 regulators requiring 3 days for familiarisation at a cost of £900 per day.

5.13 **Cost of regulators producing procedural guidance**: The one-off cost of regulators producing new guidance is estimated at £45,000. This is based on 50 days of regulatory staff time at a cost £900 per day.

5.14 **Cost of industry producing procedural guidance:** The one-off cost to industry for producing procedural guidance is estimated to be £5.4 million. This is based on 3,658 extensive users requiring 5 days to produce guidance at a cost of £250 per day giving a cost of £4.6 million; and 17,243 non extensive users spending 0.2 days at a cost of £250 per day giving a cost of £860,000. It should be noted that the time estimate provided for non-extensive users

reflect an average and not all businesses will have a cost of producing guidance as they will be unaffected by the revised regime.

The total costs are therefore estimated at £11.3 million, of which £11.1 million are identified as costs to business.

Benefits

5.15 The main monetised benefits highlighted in paragraph 5.3 are detailed below:

5.16 **All users - reduced compliance time:** Recurring discounted benefits for all users resulting from reduced time spent using EOs demonstrating compliance is estimated at £16.1 million. This is based on a combination of 3,850 extensive users spending 1 day less time ensuring compliance with the exemptions regime at a rate of £250 per day giving a discounted benefit of £8.28 million; and 18,150 non extensive users spending 0.2 days less time ensuring compliance with the regime at a rate of £250 per day giving a discounted benefit of £7.8 million. It should be noted that the time estimate provided for non-extensive users reflects an average because not all businesses will be affected by the revised regime.

5.17 **RPAs - reduced time spent advising on EOs:** Recurring discounted benefits for RPAs from reduced time spent advising users on demonstrating compliance under the new exemptions regime is estimated at £3.55 million. This is based on 550 RPAs, saving 1 day on EO matters at a rate of £750 per day.

5.18 **New user - reduced cost of familiarisation**: Recurring discounted benefits for new users from reduced costs of familiarisation is estimated at £1.2 million. This is based on a combination of 192 extensive users spend 2 days less time familiarising themselves with the new exemptions regime (compared with the existing regime) at a rate of £250 per day giving a discounted benefit of £830,000; and 908 non extensive users spending 0.2 days less familiarising themselves with the regime at a rate of £250 per day giving a cost of £390,000. It should be noted that the time estimate provided for non-extensive users reflect an average and not all businesses will have a reduced cost of familiarisation because they are actually not aware that they are using the exemption regime e.g. smoke detector users.

5.19 **Regulators – reduced time spent dealing with EO queries**: Recurring discounted benefits to regulators for reduced time dealing with calls for advice about the exemptions regime is estimated at £1.4 million. This is based on 60 regulators, saving 3 days dealing with EO matters at a rate of £900 per day.

The total recurring discounted benefits are therefore estimated at £22.3 million, of which the discounted benefits to business are estimated at £20.9 million.

Overall estimated discounted net benefit value of £11.0 million, of which the net benefit to business is estimated at £9.8 million.

5.20 During the development of the new regime, the non-monetised benefits which have been identified as important by stakeholders include:

Perception: - The use of proportionate, risk-informed regulation, which is transparent in its derivation will increase confidence of users in the regulatory process, and to society in general.

Trade: - Harmonisation with other national and international legislation and standards, which may have a positive effect on matters such as international trade.

New Business: - The proposals will introduce a simpler system with comprehensive guidance which will create an environment that is more conducive to new business start-up.

Regulatory: - A measure of future-proofing which will make the regime easier to amend in the future and reduce policy development costs in the future by relegating as much detail as possible from regulation to guidance.

5.21 A summary table of costs and benefits for the new regime is presented on page 17.

One-in, one-out

5.22 For the purposes of OIOO, prices need to be discounted from 2011 to 2009 prices. The net benefit to business, £9.8m, is therefore £9.3m after discounting. Using the OIOO formula and a time period of 10 years, this gives an OUT of £1.1m.

New exemptions regime summary of costs and benefits

		One-off	Recurring
COST TO BUSINESS (present value)	One-off transition cost of familiarisation with the new regime for existing EO users	£3.61 million	0
	One-off transition cost of familiarisation with the proposed regime for RPAs	£2.06 million	0
	One-off cost for industry producing internal procedural guidance	£5.44 million	0
Total Cost to Business		£11.11 million	0
COST TO REGULATORS (present value)	One-off transition cost of familiarisation with the new regime for regulators	£0.16 million	0
	One-off cost for regulators producing procedural guidance for industry	£0.05 million	0
Total Cost to Regulators		£0.21 million	0
TOTAL NPV COSTS		**£11.3 million**	**0**
BENEFITS TO BUSINESS (present value)	Recurring benefits for RPAs from reduced time spent using EOs demonstrating compliance	0	£3.55 million
	Recurring benefits for all users from reduced time spent using EOs demonstrating compliance	0	£16.10 million
	Recurring benefits for new users from reduced costs of familiarisation with the exemptions regime	0	£1.22 million
Total Benefits to Business		0	£20.87 million
BENEFITS TO REGULATORS	Recurring benefits to regulators for reduced time dealing with calls for advice about the exemptions regime	0	£1.39 million
Total Benefits to Regulators		0	£1.39 million
TOTAL NPV BENEFITS		**0**	**£22.3 million**
NPV (calculated over 10 years)		**£11.0 million**	

Sensitivity of net benefits of revised regime to key assumptions

5.23 The Net benefits of the new exemptions regime are sensitive to the assumptions made. The key assumptions are:

- Rate costs per day for users, RPAs and regulators; and
- Input time savings/costs for users, RPAs and regulators.

5.24 Below, we have examined the sensitivity of the net benefits by changing the input values for these central assumptions.

Rate costs for users, specialists and regulators

5.25 To examine the sensitivity of net benefits to the rate cost of users, RPAs and regulators time we:

- hold the population number in 2011 constant (22,000 users, 550 RPAs and 60 regulators);
- hold the time savings/costs for users, RPAs and regulators at their central values; and
- vary the rate cost of users, RPAs and regulators as summarised in the table below:

Scenario	Low	Central	High
Regulator time in £/day	***800**	**900**	***1300**
Specialist time in £/day	****625**	**750**	****1250**
User time in £/day	**150**	**250**	**350**
NPV (£ million)	**£7.3m**	**£11.0m**	**£15.8m**

*The rate costs used in the assumptions for regulators time (£700 – £1500 per day) have been adjusted in this sensitivity test to £800 - £1300/day as there is not a case for all 60 regulators to be solely engaged in either the non-nuclear work (£700/day) or nuclear work (£1500/day).

**The rate costs used in the assumptions for RPAs time (£500 – £1500 per day) have been adjusted in this sensitivity test to £625 – £1250/day as there is not a case for all 550 RPAs to be solely engaged in either the non-nuclear work (£500/day) or nuclear work (£1500/day).

Input time savings/costs

5.26 To examine sensitivity of net benefits to the time savings/costs for users, RPAs and regulators to the new exemptions regime we:

- hold the number of existing users in 2011 constant at 22,000;
- hold the rate costs of users, RPAs and regulators at their central value; and
- vary the time savings/costs as summarised in the table below:

Scenario		Low	Central	High
COSTS				
Users costs of familiarisation with the new regime	Extensive user	2 days	3 days	4 days
	Non-extensive user	0.1 day	0.2 day	0.3 day
RPAs costs of familiarisation with new regime		4 days	5 days	6 days
Regulators costs of familiarisation with new regime		2 days	3 days	4 days
Regulators – costs of producing guidance		40 days	50 days	60 days
Industry – costs of producing guidance	Extensive user	4 days	5 days	6 days
	Non-extensive user	0.1 day	0.2 day	0.3 days
BENEFITS				
Time savings for all users demonstrating compliance with exemptions regime	Extensive user	0.5 day	1 day	1.5 days
	Non-extensive user	0.1 day	0.2 day	0.3 day
New user reduced cost of familiarisation with exemptions regime	Extensive user	1 day	2 days	3 days
	Non-extensive user	0.1 day	0.2 day	0.3 day
Reduced RPAs time spent advising on EO regime		0.5 day	1 day	1.5 days
Reduced regulator time for handling enquiries		2 days	3 days	4 days
NPV (£ million)		£3.2m	£11.0m	£18.7m

Summary of sensitivity results

5.27 The most pessimistic set of assumptions (from all low rate cost/day and all low input time) results in net benefits (NPV) of £2.2 million.

5.28 The most optimistic set of assumptions (from all high rate cost/day and all high input time) results in net benefits (NPV) of £27.0 million.

6. Specific Impact Checklist

6.1 Each of the tests in the Specific Impact Checklist are considered below.

Competition Assessment

6.2 Considering the four questions posed in the competition assessment laid out by the Office of Fair Trading, the proposed regime is not expected to either directly or indirectly limit the number or range of suppliers. It is not expected to limit the ability of the suppliers to compete or to reduce suppliers' incentives to compete vigorously.

Small Firm Impact Assessment

6.3 The proposals are not anticipated to negatively affect small businesses, their customers or their competitors. Indeed any proposal which is proportionate and reduces administrative burden should not disproportionately affect small firms and may help as they will spend a lower proportion of their time on administrative tasks. By the nature of the material regulated it is not possible to remove impact on small businesses completely but by reducing administrative burdens its benefits will be greatest for small businesses who have less time to spend on administration.

Sustainable Development

6.4 The new exemptions regime is expected to have no material impact on sustainability, as they are not expected to materially change waste management practices.

Legal Aid

6.5 The policy is not going to introduce any new criminal sanctions or civic penalties. The proposals should therefore not have an impact on legal aid.

Health Impact Assessment

6.6 The policy proposals will not have an impact on health or health inequalities by virtue of its effects on the wider determinants of health contained in the Department of Health's screening questions for health impact assessment**.** The level of health protection provided by the legislation has not been changed.

Carbon Assessment

6.7 It is not considered there will be significant effects on emissions of greenhouse gases as a result of the implementation of this policy because the way activities are undertaken will not alter. Therefore, a full carbon assessment is not appropriate.

Equality Assessment

6.8 An initial screening of the equality impacts of this policy has been conducted. This has been completed in line with the Public Sector Equality Duty, due to come into force from April 2011, considering the equality impacts on the protected characteristics of: age; disability; gender reassignment; marriage and civil partnerships; pregnancy and maternity; race; religion or belief; sex; and sexual orientation. The policy has been assessed using the specific screening questions set out in the EHRC guidance on equality impact assessments (see page 25 of http://www.equalityhumanrights.com/uploaded_files/eiaguidance.pdf). Based on the answers to these questions, we have decided that a full equality impact assessment is not required and that the policy is not expected to have any negative equality impacts.

Human Rights

6.9 There are no human rights issues raised by these proposals.

Rural Proofing

6.10 The policy is most unlikely to have a different or disproportionate impact in rural areas due to particular rural circumstances or needs.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)];
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]

Annex 2

Options Development and the Preferred Option

This review has involved significant stakeholder engagement with experts from Government, the Health Protection Agency, environmental regulators, industry/public sector experts and

NGOs who have been involved in the development of the options from the original stages looking at what this review should consider (carried out in 2006/2007), through to the preferred option under consideration in this impact assessment.

Outcomes of the options assessment

The matrix below summarises the six options considered during the options assessment. Further details about the options assessment process and details (including the merits and disadvantages of each option) can be found in the 3 reports (***Ref 2, 3*** **and** ***4***).

Table 1: Summary of main architecture options for assessment

<table>
<tr><th rowspan="4">Option 1 – do nothing</th><th rowspan="4">Option 2 – minor updates of existing EOs</th><th>Option 3 – full updates of existing EOs</th><th>Option 4 – rebrigading of EOs</th><th>Option 5 – top level EOs with all the detail in schedules</th><th>Option 6 – goal setting/dose based approach</th></tr>
<tr><td colspan="3">Reappraisal of numerical values</td><td>N/A</td></tr>
<tr><td colspan="4">Reappraisal of the Substances of Low Activity Exemption Order – including material specific clearance/exemption levels for bulk quantities</td></tr>
<tr><td colspan="4">Reappraisal of Schedule 1 – possible change to a qualitative approach to exclusion</td></tr>
<tr><td></td><td colspan="5">Revocation of some EOs</td></tr>
<tr><td></td><td colspan="5">Guidance on operation of EO regime</td></tr>
</table>

Options assessment outcome

Whilst Options 3, 4 and 5 would produce similar end results, as a result of the options assessment process (using multi-attribute analysis), Option 5 was agreed by experts as the preferred framework for the EO regime, with one minor modification suggested that there should only be one exemption order and not two. In summary it was considered that option 5:

- was the most compatible with other better regulation initiatives such as the Environmental Permitting Regulations and other environmental protection legislation;

- was very adaptable to new circumstances and practices;

- had the potential to lower the regulatory burden if done well;

- would be risk-informed.

Preferred Option development process

Following the option assessment process, detailed work was undertaken to populate the preferred EO framework (Option 5) with numerical values and conditions. It was during the

course of this detailed work to develop a new exemptions regime, that it became apparent that attention to the scope of RSA 93 was important in order to provide a comprehensive and logical regime. This aspect was therefore added to Option 5, and an expert group was convened which made recommendations (***Ref 5***) as part of this review.

A workshop (***Ref 6***) was held to test the inputs to the proposed new framework and the general principles were accepted by stakeholders.

A full public consultation exercise took place from June to September 2009; a link to the consultation document and supporting material can be found here (http://www.decc.gov.uk/en/content/cms/consultations/exemptions/exemptions.aspx).

The consultation exercise raised a number of issues which required change to the detailed provisions to avoid a significant burden to a variety of industries; the consultation response summary document (***Ref 7***) summarises these issues.

An expert group comprising technical experts from Government, the environmental regulators, the Health Protection Agency (HPA), and external consultants made recommendations to revise the proposals following the consultation, with the changes proposed being modifications to details and expansion of some of the provisions (an important case in point being the extension of the exemptions regime to deal with naturally occurring radioactive material (NORM) wastes in significant volumes). The work of this group was supplemented by inputs from industry and professional associations, who were contacted throughout the process on specific technical matters. Firm proposals for the preferred option for a new exemptions regime were developed around these key changes/issues. To understand the impact of these changes, it was appropriate to test these through further stakeholder engagement in September 2010 (the stakeholder engagement material can be found here (http://www.decc.gov.uk/en/content/cms/what_we_do/uk_supply/energy_mix/nuclear/radioactivity/decc/legislation/exempt_review/stakeholder/stakeholder.aspx).

The stakeholder engagement exercise identified areas where additional refinement was required. Further work with experts from the HPA, environmental regulators and industry has resulted in changes, including:

- Simpler proposals for stakeholders to understand, including the scope of exemptions and transitional provisions
- Clarification on whether the limits for NORM industrial activities would apply solely to the wastes produced or to the material also
- Further clarity with definitions
- Extension of NORM waste provisions to apply to legacy wastes
- Extension of provisions for non-aqueous and aqueous liquids

Preferred option summary

The preferred option will modernise the definitions of radioactive material and waste in RSA93 and replace the 18 EOs with a single, consistent, conditional EO. The effect of this will be to change the boundaries of what is outside the scope of legislation; what is exempt from full regulation and what is subject to permitting. Currently legislation places material and waste into one of the following 3 categories:

- Excluded ('out of scope') from legislation. Materials and wastes in this category are of such low radiochemical concentrations that they pose an extremely low risk to members of the public – the radiation doses are extremely low whatever the chemical or physical nature of the materials or wastes, and whatever is done with them (e.g. any

form of uncontrolled disposal of waste). Also within this category are materials or wastes which cannot practically be controlled; an example of this is radioisotopes that are in circulation in the atmosphere as a result of atomic weapons testing in the 1960s. No practical permitting regime can be applied to this situation, but fortunately the risks (in terms of a radiation dose) are extremely low.

- Exempted materials and wastes. This category is for materials and wastes which pose a small risk in terms of radiation dose, but the risks are low enough such that a 'light touch' regulatory approach is appropriate and proportionate. This light touch approach does not involve applications to, or permitting by, the regulators. However, the management of such materials and wastes has to be subject to certain conditions; that is, uncontrolled disposal in unlimited quantities may compromise the well established risk criteria. Therefore, the current exemption regime is largely conditional. The proposed regime is entirely conditional.

- Materials and wastes which are subject to full regulation, involving direct permitting by the regulators. Such materials and wastes could pose significant risks, and in order to ensure that the safety criteria are not compromised, then case- or site-specific conditions have to be applied. This is done by way of a bespoke permit, and the conditions are audited by way of regulatory inspections.

The proposed regime retains this principle but makes changes to the boundaries between the categories for 3 reasons:

- The current boundaries are in the wrong place. Whilst the current boundaries are based, in part, on risks, 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, we have redrawn the boundaries and made them substantially clearer.

- 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. Decisions of this nature are often taken with advice from the regulators, taking up their time as well as that of the users or waste managers. The new regime clears up a substantial number of these difficult areas.

- There are gaps in the boundaries because the current exemption orders are up to 50 years old, and technology in this field continually advances. There are situations which are quite obviously of low risk (and can be proven so), but are not exempted under the current legislation. Again, resolving these situations often involves advice from the regulators, who can sometimes be put at risk by making certain practical and essential judgements which could be challengeable from a legal perspective. The new regime, following widespread consultation with experts, waste managers, regulators etc, has filled in a substantial number of these gaps to provide users and waste managers with a continuous set of boundaries.

These changes to the boundaries between exclusion, exemption and permitting have received universal acceptance by our stakeholders. They have welcomed the clear risk-informed (and transparently fair) 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 an approach which not only fills in the gaps in the boundaries as perceived today, but attempts to future proof the legislation such that many currently unforeseen developments could be accommodated within the new structure (in a way that the current legislative situation does not).

The regime will be supported, for the first time, by comprehensive guidance written by Government in order to explain to the regulators (and, by extension, users) the intent of the various exemption provisions. This guidance will be supplemented with more detailed guidance prepared by the environmental regulators.

Impacts

The changes described above will simplify the existing regime and the following examples demonstrate how this will affect stakeholders on the ground.

Medical/research sector

A research laboratory manager requires advice on the quantities of exempt aqueous liquid which can be disposed of to a laboratory sink and what conditions apply. In the course of dispensing the liquid, some will be emitted to a fume cupboard as a gas. There are two elements to this example – exempt gaseous release and exempt aqueous disposal. As far as gaseous disposal is concerned, under the present regime, there is no clear or explicit legislation or guidance on exempt gaseous releases. This will be rectified in the proposed regime. Currently, in determining whether the new activity is exempt or not, a RPA would have to:

- refer to the existing suite of numerous exemption orders. These have different limits which, sometimes, are not consistent with each other. The proposed discharges would need to be compared with these values;

- refer to Environment Agency (EA) guidance notes and other EA published determinations from, for example, the small users liaison group technical services updates;

- discuss with the EA (local Inspector and/or EA Technical Services);

- discuss with RPA colleagues in other organisations, either directly or by professional mailbases.

The RPA would then have to write a guidance and advice note for the laboratory manager which, if exemptions could be used, would need to detail the conditions (of the exemptions) under which the activity should be carried out. The content of these conditions, including numerical values and administrative provisions, would need to be ascertained from a number of sources.

Under the proposed regime, reference would have to be made to only one guidance document where:

- the position in respect of both gaseous and liquid disposals is clearly set out.

- all conditions applying to the exemptions are contained in one clearly referenced page of the guidance. This includes both numerical limits and administrative conditions.

Then, the guidance and advice note for the laboratory manager would have to be produced. In this case, the operational conditions could be copied/pasted directly from the guidance document, or the relevant page(s) from guidance copied and supplied directly to the laboratory manager. This work would be significantly less time consuming, and likely to take approximately 2 hours to produce compared to 6-7 hours under the current regime.

Nuclear site variation

A nuclear site wishing to excavate an area for a new plant, which pumps out tritium-contaminated water would currently have to apply for a variation to their permit. Under the new

regime they would have to notify the regulators and seek a new schedule to be added to their permit. They would not have to do a radiological impact assessment for the new waste stream, because a generic one has already been carried out under the EO review programme.

Under the existing regime the authorisation variation would require the following effort:

- Completion of application forms - 1 man day
- Supporting report setting out proposal - 4 man days
- Dose assessment (simple scaling approach) - 0.5 man day
- Preparation of covering letter - 0.5 man day
- Changes to reporting forms, spreadsheets, procedures etc - 2 man days
- Support and monitoring of the application and consultation: - 2 man days

Under the revised regime the following effort would be required:

- Letter requesting EO provisions - 0.5 man day
- Changes to reporting forms, spreadsheets, procedures etc - 1.5 man days
- Support and monitoring of the application - 0.5 man days

It is not possible to scale up this example to a national position for all nuclear sites over time because we have no information relating to the frequency of this event historically. For each occurrence, the cost savings are estimated to be around £3250.

Schools

RPAs get requests for advice on the disposal of redundant sealed sources. The main questions relate to the exempt nature of the source disposal and what conditions would apply to the disposal.

Under the current system this will entail reference to several exemption orders, EA guidance and possibly the EA helpdesk and precedents. It will involve calculations, including unit conversion, from one or more (sometimes inconsistent) exemption orders, followed by a comparison with the source in question. A list of the exemption conditions from one or more (sometimes inconsistent) exemption orders will the need to be compiled before the RPA can produce an advice note to the school on whether the source can be disposed of using an exemption order.

Under the revised regime, the RPA would need to make simple reference to the government guidance which deals with sealed sources and sets out activity limits for exemption and the administrative conditions associated with it. This would also provide the basis of the advice note the RPA would provide to the school.

Start up company

A manufacturer of scientific equipment wishes to branch out into a new line that requires the use of a small test source is an example of how the current exemption regime is restrictive and deters innovation and adds costs for new start. Manufacturers are not currently able to use the existing Testing Instruments Exemption Order. So a start up company would need to have a Category 5 Standard Rules Permit (Type B to allow for disposals) at an application cost of £600 and an annual subsistence fee of £300 together with the cost of an RPA to complete all the paperwork for them at a cost of around £600. Under the new system they would be exempt if they do not exceed the inventory limit. We cannot scale up these costs to a national picture

because we have no information as to how many similar situations are likely to occur, or have occurred historically.

Regulators

The Environment Agency have estimated that currently, on average, an RSR regulator/technical advisor/manager (60FTE) will spend approximately 3% of their working year on dealing with issues related to advice, guidance and interpretation of exemption provisions and the definitions of radioactive material and radioactive waste. Some of this time will be dealing with enquiries from EPR permit-holders who also use the current exemption orders, and some will be dealing with those who operate wholly within the exemption regime. None of this work is chargeable to the customer. The enquiries fall into a number of categories, typically they are of the type is my new sources/products exempt? Is my waste radioactive waste? Is my radioactive waste exempt? Can I use the exemption? What am I allowed to do with my exempt waste? What do the conditions mean? What do I need to do to comply with the conditions? How many sources can I hold under the exemption?

Many of the most time consuming issues that are dealt with by regulators are those related to very low concentration radioactive substances, deciding whether a waste is "out of scope", exempt or at the threshold of permitting. These cases have often been more difficult than determining whether a waste is Low Level Waste or Intermediate Level Waste. This in part is because of sampling and measurement issues, both of which will be addressed in guidance supporting the new regime.

Under the revised regime, with modern limits and conditions, underpinned by national assessments of risk carried out by the Health Protection Agency, together with comprehensive guidance from government and the regulators, it should be possible for most of the advice and guidance work the regulators do now by telephone and email to be avoided by directing customers to web based guidance. They forecast that these enquiries will, after the exemption provisions have bedded down, reduce by more than 50%, and that in addition because of the existence, for the first time, of comprehensive guidance, each enquiry should be able to be dealt with more quickly than previously. There has been a conscious effort made in the development of the new provisions to deal with the issues and sectors that have been the principal sources of these enquiries e.g. laboratories undertaking lifescience, pathology and tracer work generating small quantities of liquid radioactive waste, which will now be exempt.

In summary, the regulators believe that by providing exemption provisions to deal with a wider range of low-risk users/substances, together with comprehensive web-based guidance, it should conservatively reduce the current 3% figure to 1-1.5% once the regime has bedded down.

New User

It is very difficult to provide examples of the benefits of the revised exemptions regime to new users of radioactive material because by definition we do not know who they are. However, a recent example came to light when a manufacturer wanting to use a sealed source for measuring the rate of flow in a smart meter sought advice on when the new regime would be coming into force. They wished to make use of the proposed exemption for sealed sources because it was not clear to them that they were exempt under any existing exemption order. Feedback from the organisation was that the proposed regime clearly stated the level of alpha and beta activity for a sealed source for manufactured articles, which covered their application and the conditions of the exemption were also clearly stated. In the current regime they felt it was harder to understand which exemption order would cover the meter and they had sought confirmation from the regulators that it was exempt under the existing Testing Instruments Exemption Order which was not immediately clear to them. From their experience

they estimate that whilst it had taken approximately 4 days to understand the current regime this had been reduced to 2 days to understand the revised regime with its associated guidance.

Annex 3

Meeting Note

Summary Note - Meeting to discuss the EO Review Impact Assessment (22/12/2011)

Location: LG04, 3 Whitehall Place
Attendance: Binika Shah (DECC)
Anthony Moulds (DECC Economist)
By telephone conference:
Fiona Shand (DECC)
Allan Ashworth (DECC)
Stuart Hudson (Scottish Government)
Bob Russ (EA)
Adam Stackhouse (SEPA)
Chris Fayers (Clearance and Exemption Working Group – nuclear industry liaison)
Richard Harrison (Association of University Radiation Protection Officers – non-nuclear industry liaison)

1. Everyone was thanked for their input on the paper containing the impact assessment methodology which was circulated at the Programme Board meeting on 16 December and the subsequent spreadsheet circulated on 20 December. Following comments received and further discussions at the subsequent meeting on 20 December, the version of the spreadsheet circulated in advance of this meeting had taken on board the following comments:

    - The day cost estimates had been revised for users.
    - A day cost bias had been incorporated for the environmental regulators and RPAs (based on ratios indicated from the split of nuclear and non-nuclear permits).
    - The user pool had been split into extensive and non-extensive users with indicative estimates of costs and benefits incorporated, based on limited data from industry responses and estimates from environmental regulators based on the types of permit holders.
    - The number of environmental regulators dealing with queries relating to EOs had been revised, based on further investigations by the environmental regulators throughout the UK.

2. Both the nuclear industry and non-nuclear industry representatives had circulated the IA to their networks but very few responses had been received. It was reiterated that although the draft IA had been circulated to all stakeholders contacted as part of the engagement exercise, with the lack evidence provided relating to the benefits, it would not be possible to include specific data. It was therefore agreed that a judgement would need to be made on the costs and benefits based on the expertise available.

3. It was agreed that the methodology would not need to change further; the types of costs and benefits had been adequately identified and no others were identified; there was the potential that once the regulations were laid and tested, further information would come to light when undertaking the post implementation review.

4. Running through the spreadsheet circulated in advance of the meeting, the following changes were agreed:
    - The day costs for users still appeared to be a bit high, it would need to be reduced further; £250 was agreed to be a fair estimate.
    - The number of days for familiarisation and producing guidance for a non-extensive user appeared to be too high; 0.2 days for each was more appropriate.
    - The time saved by all non-extensive users demonstrating compliance was likely to be greater; 0.2 days was considered more appropriate.

    The agreed table can be found in the appendix below; the ranges would need refining further in light of these changes but were deemed to be of the right order of magnitude. This would then be circulated for final agreement.

5. It was agreed that the table would then be circulated to a small group of stakeholders from a variety of industries to check whether these estimates would be acceptable.

6. In terms of next step, this information would now be fed into the IA which was being developed further following the close of the engagement, and would be submitted to the Regulatory Policy Committee in spring 2011 (as per the timetable). Scottish Government and Department of Environment Northern Ireland had heard that they would need to submit their own impact assessments; they would use this methodology and submit as per their respective timetables.

EO Review Team
January 2011

Post meeting note

Response from stakeholders was that, appreciating that each circumstance for individual industries would result in monetary variations, the cost and benefit estimates used in the IA were deemed acceptable.

Appendix

One-off Transition Cost Assumptions

1	***Existing users - cost of familiarisation with new EO regime***	
	Extensive existing users (i.e. 95% of pool)	3,658
	Cost of familiarisation with new regime (£ / day)	250
	Number of days input required for intensive users	3
	Non-extensive existing users (net of new entrants)	17,243
	Cost of familiarisation with new regime (£ / day)	250
	Number of days input required	0.2
2	***RPAs - cost of familiarisation with new EO regime***	
	Number of RPAs	550
	Cost of familiarisation with new regime (£ / day)	750
	Number of days input required	5
3	***Regulators - costs of familiarisation***	
	Number of RSR regulators	60
	Costs of familiarisation with new regime per regulator / day	900
	Number of regulator days required for familiarisation with new regime	3
4	***User Guidance - cost of producing new guidance***	
	Extensive users	3,658
	Cost of developing guidance (£ / day)	250
	Number of days input to develop guidance	5
	Non-extensive users	17,243
	Cost of developing guidance (£ / day)	250
	Number of days input to develop guidance	0.2
5	**Regulator Guidance - cost of producing new guidance**	
	Number of days input	50
	Cost of developing guidance (£ / day)	900

Recurring Benefits Assumptions

1	***RPAs - reduced time spent advising on EOs under new regime***	
	Cost of professional advice for familiarisation (£ / day)	750
	Number of RPAs	550
	Number of reduced days RPA input	1
2	***All users - reduced time spent using EOs***	
	Extensive users	3,850
	Average user cost (£ per day)	250
	Reduction in EO use due to simplification (days / year)	1
	Non-extensive users	18,150
	Average user cost (£ per day)	250
	Reduction in EO use due to simplification (days / year)	0.2
3	***New Users - reduced costs of familiarisation***	

Extensive new entrant users	193
User cost (£ / day)	250
estimated reduction in EO cost (days / year)	2
Non extensive new entrant users	908
User cost (£ / day)	250
estimated reduction in EO cost (days / year)	0.2

4 ***Regulators - reduced time for handling enquiries***

Number of RSR regulators	60
Estimated cost of handling telephone calls (£ / day)	900
Reduction in time spent per regulator handling calls (days / year)	3