Title:	Impact Assessment (IA)
Impact Assessment of the Review of the Exemption Orders under the Radioactive Substances Act 1993 **Lead department or agency:** DECC **Other departments or agencies:** DEFRA & Devolved Administrations	**IA No:** DECC0011 **Date:** 11/08/2010 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Stephen Allen 0300 068 6101

Summary: Intervention and Options

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

The Radioactive Substances Act 1993 is a prior permitting regime for the keeping and use of material; and disposal of radioactive waste. Exemption Orders are a mechanism for providing a degree of control, without excessive bureaucracy, over minor uses of radioactive substances where there is a clear benefit from use, whilst ensuring continued protection of the environment and the public. Government intervention is required across the UK to produce a new Exemptions regime which meets modern requirements in relation to practicality, legal robustness and a proportionate (i.e. risk-informed) regulatory burden.

What are the policy objectives and the intended effects?

To produce a simpler, less burdensome exemptions regime including a clearer scope of regulation for stakeholders working with radioactive substances whilst at the same time maintaining the necessary protection for people and the environment.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

We are seeking a call for evidence on the three options presented in this impact assessment: a do nothing option (Option 0), updating the existing EOs (Option 1) and introducing a new top level Exemptions regime (Option 2). The 'top level' option, which involves a significant rationalisation and simplification of the current regime was the clear preference, following extensive stakeholder engagement, and we believe that it will bring the highest net benefits. Please note that an options assessment covering six options for the framework of the new exemptions regime was considered by expert stakeholders from a variety of disciplines (see annex 1 for more information).

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 04/2012
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

SELECT SIGNATORY Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY:..... Date:.....

Summary: Analysis and Evidence

Policy Option 1

Description:

Minor Updates to Existing Regime

Price Base Year 2010	PV Base Year 2010	Time Period Years 20	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate: 4.40**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0.70		0	**0.68**

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

Minor costs borne from familiarisation of users regulators and specialist advisers with revised regulations and new guidance

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

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	20	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0.36	**5.08**

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

Revised regulations and new guidance would make the exemptions regime easier to understand and reduce the need for new users to seek specialist advisers advice

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

The current 18 EOs which are still required would be revised using clear unambiguous language, SI units, up to date references, a consistent layout across all the EOs including harmonising conditions, checking consistency with other legislation and updating coverage.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There are approximately 22,000 users of EOs in UK and 2200 permit holders (10 users/permit holder), utilising 3850 permits. Daily cost of RPAs and regulators on exemption order related work is £500 and £1100 respectively; RSR Regulators currently spend around 3% of their time dealing with EO related queries; All 22,000 users are expected to consult with their RPAs on exemption order related work; It is estimated that around 1100 new operators per year would wish to use the exemptions regime (based on 5% new applications, 193 new permits/y or 110 new companies/y). The number of users entering and exiting the regime will be similar so the overall population will remain neutral; The new regime will last for perpetuity but the NPV calculation is based on 20 years

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB: N/C	**AB savings:** None	**Net:** N/C	**Policy cost savings:** 0.1/y	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			01/04/2011		
Which organisation(s) will enforce the policy?			Environmental Regulators		
What is the annual change in enforcement cost (£m)?			No change		
Does enforcement comply with Hampton principles?			Yes/No		
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:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	Yes/No	Yes/No	Yes/No	Yes/No	Yes/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	17
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	16
Small firms Small Firms Impact Test guidance	No	16
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	16
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	16
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	16
Human rights Human Rights Impact Test guidance	No	17
Justice system Justice Impact Test guidance	No	16
Rural proofing Rural Proofing Impact Test guidance	No	17
Sustainable development Sustainable Development Impact Test guidance	No	16

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 2

Description:

Top Level - Rationalisation and Simplification of Existing Regime

Price Base Year 2010	PV Base Year 2010	Time Period Years 20	Net Benefit (Present Value (PV)) (£m)		
			Low: 6.97	**High:** 11.20	**Best Estimate: 8.93**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0.73	1	0	**0.69**
High	1.83		0	**1.76**
Best Estimate	1.28		0	**1.23**

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

Medium costs borne from familiarisation of users, regulators and specialist advisors with significantly revised new exemptions regime, regulations and new guidance

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

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low		20	0.58	**8.21**
High			0.85	**12.12**
Best Estimate			0.72	**10.16**

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

New exemptions regime and guidance would make the regime easier to understand and reduce the need for new users to seek specialist advisors advice.

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

The proposals will introduce a simpler system (from 18 EOs to 1EO).
Use of proportionate, risk informed regulation, will provide confidence to society.
Harmonisation with other national and international legislation and standards.
The new regime responds positively to stakeholder demands for a revised exemptions regime .Relegation of as much detail as possible from the statutory instrument to guidance (future proofing).

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There are approximately 22,000 users of EOs in UK and 2200 permit holders (10 users/permit holder), utilising 3850 permits. Daily cost of RPAs and regulators on exemption order related work is £500 and £1100 respectively; RSR Regulators currently spend around 3% of their time dealing with EO related queries; All 22,000 users are expected to consult with their RPAs on exemption order related work; It is estimated that around 1100 new operators per year would wish to use the exemptions regime (based on 5% new applications, 193 new permits/y or 110 new companies/y). The number of users entering and exiting the regime will be similar so the overall population will remain neutral; The new regime will last for perpetuity but the NPV calculation is based on 20 years.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB: N/C	**AB savings:** None	**Net:** N/C	**Policy cost savings:** 0.2/y	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Options		
From what date will the policy be implemented?			01/04/2011		
Which organisation(s) will enforce the policy?			EA		
What is the annual change in enforcement cost (£m)?			No change		
Does enforcement comply with Hampton principles?			Yes/No		
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:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	Yes/No	Yes/No	Yes/No	Yes/No	Yes/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.

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Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[2] Statutory Equality Duties Impact Test guidance	No	17
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	16
Small firms Small Firms Impact Test guidance	No	16
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	16
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	16
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	16
Human rights Human Rights Impact Test guidance	No	17
Justice system Justice Impact Test guidance	No	16
Rural proofing Rural Proofing Impact Test guidance	No	17
Sustainable development Sustainable Development Impact Test guidance	No	16

[2] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB 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 assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	
2	
3	
4	

+ Add another row

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	1.260	0	0	0	0	0	0	0	0	0
Annual recurring cost	0	0	0	0	0	0	0	0	0	0
Total annual costs	0	0	0	0	0	0	0	0	0	0
Transition benefits	0	0	0	0	0	0	0	0	0	0
Annual recurring benefits	0.675	0.675	0.675	0.675	0.675	0.675	0.675	0.675	0.675	0.675
Total annual benefits	0	0	0	0	0	0	0	0	0	0

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

Microsoft Office
Excel Worksheet

Evidence Base (for summary sheets)

1. Purpose and intended effect

Objective

1.1 Government's better regulation agenda aims to simplify regulations, by reducing the regulatory burden on industry through improvements in regulation. The Exemption Order (EO) review, which is re-evaluating the scope of regulation and exemption from some of its 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 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.

Background

1.2 The Radioactive Substances Act 1993 (RSA 93) 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. Its intent is the protection of human health and the environment from risks from the disposal of radioactive waste. Schedule 1 of the Act gives maximum activity limits for naturally-occurring radioactivity below which the Act does not apply. EOs are a 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.

1.3 The first Radioactive Substances Act (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.

1.4 Responsibility for the subject matter of the RSA 93 lies with the administrations in England, Scotland, Wales and Northern Ireland and is administered by the environmental regulators across the UK.

1.5 Since the 2009 consultation on a future exemptions regime (see Annex 1 for more information), RSA93 has been repealed and migrated into the Environmental Permitting Regulations 2010 (EPR 10) in England and Wales (except for exemption order provision). The outcome of the proposals under consideration in this impact assessment will therefore be incorporated directly into EPR in England and Wales. In Scotland and Northern Ireland, the scope of RSA93 will be amended by regulations under the European Communities Act 1972 and their new Exemption Orders will be made at the same time.

1.6 For the purposes of this document we refer to both EPR 10 and RSA 93 as RSA 93

Rationale for Government Intervention

1.7 The reasons for the Exemption Order (EO) review and the consultation process to date are set out in the June 2009 consultation document entitled "Proposals for A Future Exemptions Regime under The Radioactive Substances Act 1993 and The Environmental Permitting Regulations 2010 **link to 1st consultation website**. The rationale for the review is summarised below.

1.8 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.

- 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.

1.9 In addition, recent experience has shown that even minor changes to existing EOs is time and resource intensive. Reviews by legal specialists carried out on a request to make such minor modifications to some paragraphs show that these modifications often have ramifications for other paragraphs, for other EOs, or even for the Act itself.

1.10 A wholesale review of EOs is therefore believed to be overdue. 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. There has been widespread pressure from a number of constituencies, including operators, regulators, other 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 Radioactive Waste Policy Group in February 2006. By undertaking this review, it is hoped that 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. Without a change to the exemptions regime there would be decreased confidence by users of the regulatory process. In this paper exemption regime means both material outside the scope of regulation and exempted material

1.11 The EOs under RSA 93 have been highlighted as an area where the regulatory burden to industry could be reduced and the EO review is part of DECC's simplification plan (in response to the Government's better regulation agenda). Whilst the devolved administrations do not have an equivalent better regulation agenda they have fully adopted the spirit of the agenda where the EO review is concerned.

1.12 The principal measure of 'environmental standards' in the context of radiation protection is human health, as measured or calculated in terms of radiation dose to people. It is the Government's intention that these proposals do not change the human health protection standards currently in place. We have adopted the standards as set out in the 1996 Basic Safety Standards Directive which are currently applied through RSA 93 and associated Secretary of State Directions and Statutory Guidance to the environmental regulators.

2. Analysis of Costs/Benefits

2.1 Following feedback from the thorough options assessment carried out between 2006-08 and the 2009 public consultation, this impact assessment will consider the costs and benefits of:

- Option 0 (do nothing)

- Option 1 (minor updates and guidance)

- Option 2 (top level rationalisation and simplification of existing regime)

Proposed approach to analysis

2.2 Cost and benefit estimation for the options is problematical for two reasons:

(i) We do not know (almost by definition) how many users of radioactive substances are currently employing the exemptions regime. Because the EO regime is designed to reduce administrative burdens, no reporting to a relevant authority is necessary. There are therefore no formal records of EO users.

(ii) The difficulty of stakeholders to quantify the 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) respondents were unable to quantify the costs and benefits.

2.3 This has meant that we have been limited to considering this impact assessment in terms of professional costs of RPA time required by users to familiarise themselves with exemption orders to ensure that they prescribe to the requirements of the exemptions regime. This is because it is the one common theme that can be assessed across each option. We have referred to this as 'user time' even though it is not strictly the time users actually spend using the regime, more the costs they incur hiring a RPA to familiarise themselves with the exemption order requirements. We therefore propose to analyse the options on 'user time' (i.e. the costs/time taken for RPA's to familiarise users with the Exemptions regime).

Q.1 As a user of exemption orders, how much of your time is currently spent working with them? If possible, please include the time spent familiarising with the requirements of EOs. Please attempt to separate:

- ***User time; and***
- ***RPA time spent advising users.***

2.4 The main monetised costs and benefits of Options 1 and 2 relative to Option 0 are:

- One-off costs of familiarisation to the proposed regime for regulators and existing EO users;
- One-off costs for producing regulators guidance
- Ongoing reduced costs of familiarisation for new users; and
- Ongoing reduced costs to regulators of dealing with calls for advice about the exemptions regime

Assumptions

2.5 The estimates set out in this impact assessment are based on assumptions because of the problems highlighted above, and are consequently uncertain. The main assumptions are that:

(i) The Environment Agency believe that there are currently 3850 permits and that, on average, a permit holder has 1.75 permits totalling the current number of permit holders at 2200. The EA believe that there are at least 10 EO users for every permit holder giving a total user pool of 22,000. This is probably a reasonable order of magnitude estimate.

(ii) The daily cost of professional advice required by a user for familiarisation with Exemptions regime is £500. This is based on advice from the Society of Radiological Protection on the average consultancy rate of Radiological Protection Advisers (RPAs). All 22,000 users are expected to consult with their RPAs on exemption order related work.

(iii) The UK has around 100 Radioactive Substances Regulation (RSR) Regulators which currently spend on average 3% of their time dealing with EOs. Regulators costs range from £700/day for non-nuclear regulators to £1500/day for nuclear regulators so an average of £1100/day has been selected as an appropriate figure. This is based on advice from the Environment Agency.

(iv) The number of users entering and exiting the regime will be similar so the overall population will remain neutral. It is estimated that around 1100 new operators per year would be required to use the exemptions regime (this figure is sourced from information presented by the Environment Agency based on 5% new applications, i.e. 193 new permits/y or 110 new companies/y in UK multiplied by 10 EO users for every permit holder).

(v) The new regime will last for perpetuity but the NPV calculation is based on 20 years.

(vi) These assumptions are made for both option 1 and 2.

Q2. Do you agree with the assumptions made for Options 1 and 2 in paragraphs 2.5 and 2.16 in this Impact Assessment? If not, please provide specific examples why.

2.6 An assessment of the sensitivity of the costs and benefits estimates to the assumptions is set out in section 3 of this document

2.7 A summary table of costs and benefits, under central assumptions, is below.

Summary of Costs and Benefits

		Option 1 One-off	Option 1 Recurring	Option 2 One-off	Option 2 Recurring
COST (present value)	Existing users and regulators familiarisation with regulations and guidance	£680,200		£1,217,400	
BENEFITS (present value)	New users time savings	X	£1,954,200	X	£3,908,400
	Regulators time savings	X	£3,126,700	X	£6,253,500
	Risk informed regime	X		YES	
	Harmonisation with other national and international legislation and standards	X		YES	
	Regime future proofed	X		YES	

	Increased confidence by users of the regulatory process	X	YES
	Simpler system encourages new business to start up	X	YES
	NPV (calculated over 10 years)	**£4,400,700**	**£8,929,000**

The Options

Option 0: Do Nothing

2.8 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.

2.9 Costs and benefits of the other options are estimated relative to this baseline.

Q.3 How much time do you think a new user would take to familiarise themselves with the existing exemptions regime?

Option 1: Minor Updates

Option Summary

2.10 Those current EOs (were deemed to be still required) would be revised using clear unambiguous language, SI units, up to date references, a consistent layout across all including harmonising conditions, checking consistency with other legislation and updating coverage. Supporting guidance would also be produced. This would make it simpler for stakeholders to understand the content of the EOs. It would not, however, eradicate the disparities in the structure and philosophy, with each of the EOs having different purposes; There would be no change in the scope of the Act in the definition of radioactive material and radioactive waste.

Costs

2.11 One-off costs to existing users[3] of familiarisation to the new guidance and updated regulations through their RPA's, are estimated to be £550K. This is based on an assumed time for RPA's to familiarise each EO user with the guidance and updated regulations of 0.05 days[4], 22,000 existing EO users, and a cost per day of professional RPA advice of £500.

2.12 The EA have estimated the one-off costs to regulators to be in the region of £154K. This is based on:

[3] Existing users are those that currently use the existing exemptions regime and will be affected by changes implemented through the suggested Options as a cost.
[4] The amount of professional advice needed per existing user is based on the calculation 1100 RPA days shared between 22,000 users

- £99K cost of developing regulatory guidance (drafting, internal consultation, amending and uploading to intranet) covering the 18 different EOs estimated to be 90 man days at £1.1K/day.
- £55K cost of regulators updating themselves on the new regime is estimated at 0.5 man-day/regulator across 100 regulators at the above rate

Total one-off cost of £704.0K. discounted to £680.2K

Benefits

2.13 Revised regulations and new guidance would make the exemptions regime easier to understand through clearer presentation, harmonisation and consistency and may reduce the need for new users[5] to seek specialist advisers advice through their RPA's. Ongoing benefits to new users are £137.5K per annum. This is based on an assumed reduction in the required RPA time, relative to "do-nothing", for each EO user, with the help of new guidance and clearer regulatory language, to apply the regime of 0.25 days[6], 1100 new EO users per year, and a cost per day of professional advice of £500. The present value of these benefits is £1,954.2K.

2.14 Ongoing benefits to regulators are £220K per annum, based on forecasts estimated by the EA on reduced time of 2% spent dealing with EO (compared with 3%) due to the benefits of the detailed guidance. The present value of these benefits is £3,126.7K.

Total Benefits over 20 years £5,080.9K

Overall Benefits net present value of £4,400.7K

Q4. Are you in agreement with the estimated cost and benefits highlighted for Option 1? If not, please provide us with your best estimate for any time savings or costs.

2.15 Other non-monetised benefits that have been identified for Option 1 include the following:

- Easier to understand regulations using clear unambiguous language, SI units, update of references and coverage

Option 2: Top Level Rationalisation and Simplification of Existing Regime

Option Summary

2.16 This option would replace the present suite of 18 EOs (including amendments) with one top level EO for conditional exemption (see Annex 2 for more details of this option). This would set out the general arrangements with the detailed revised numerical values located in schedules. This would involve a significant rationalisation and simplification of the current regime and would relegate as much detail as possible to supporting guidance to provide a measure of future-proofing. The option also includes proposals for amendments to the definitions of radioactive material and radioactive waste (material outside the scope of the Act) which would appear in accompanying regulations amending RSA 93.

Assumptions

2.17 There are two additional assumptions for Option 2:

[5] New users are those that will enter the new revised exemptions regime, under either Option, and will therefore benefit from the changes.
[6] Saving in professional advice needed per new user is based on the calculation 275 RPA days shared between 1100 new users

- The option effectively reproduces the existing exemptions regime, with differences only at the margins; that is, some currently exempted practices will require permitting; and vice-versa. We have assumed that these differences are in balance for the purposes of this impact assessment, although an initial view is that the number of permitted activities will reduce slightly.

- It should be noted that during the 2009 consultation, we assumed that all the options proposed would not change waste management practices, that is, although the boundary between the exempt and permitted regimes may change marginally, waste management costs would remain as at present. This assumption was not refuted during the consultation exercise and we believe it continues to hold true in the revised proposals.

Costs

2.18 One-off costs to existing users of familiarisation to the new regime through their RPA's, are estimated to be £1100K. This is based on an assumed time for RPA's to familiarise each EO user with the regime of 0.1 days[7], 22,000 existing EO users, and a cost per day of professional RPA advice of £500. Existing users would incur higher costs of familiarisation to the proposed regime under Option 2, when compared to Option 1, as Option 1 is more similar to the current regime.

2.19 The EA have estimated the one-off costs to regulators to be in the region of £176K. This is based on:

- £66K cost of developing regulatory guidance covering the new exemptions regime involving 60 man-days at £1.1K/day. EA believe will be less involved than producing guidance for Option 1.
- £110K cost of regulators updating themselves on the new regime is estimated at 1 man-day/regulator across 100 regulators at the above rate.

Total one-off cost of £1276.0K discounted to £1232.9K

Benefits

2.20 Revised regulations from 18 EOs to 1 EO and new guidance would make the exemptions regime easier to understand and would greatly reduce the need for new users to seek specialist advisers advice through their RPA's. We believe that, in theory users, should not need to seek specialist help at all, although in the real world this may not be the case. Ongoing benefits to new users are £275K per annum. This is based on an assumed reduction in the required RPA time, relative to "do-nothing", for each EO user to familiarise themselves with the regime of 0.5 days[8], 1100 new EO users per year, and a cost per day of professional advice of £500. New users have higher cost savings from familiarisation and use of the proposed regime under Option 2, when compared to that proposed under Option 1, as we believe the regime under Option 2 is simpler. The present value of these benefits is £3,908.4K

2.21 Ongoing benefits to regulators are £440K per annum, based on forecasts estimated by the EA on a reduced time of 1% spent dealing with EO queries (compared with 3%) due to the detailed guidance and revised, simplified regime. The EA apportioned this into £220K identified against the guidance and £220K identified against the simplified regime. The present value of these benefits is £6,253.5K

[7] The amount of professional advice needed per existing user is based on the calculation 2200 RPA days shared between 22,000 users

[8] Saving in professional advice needed per new user is based on the calculation 550 RPA days shared between 1100 new users

Total Benefit over 20 years £10,161.9K

Overall Benefits net present value of £8,929.0K

Q5. Are you in agreement with the estimated cost and benefits highlighted for Option 2? If not, please provide us with your best estimate for any time savings or costs.

2.22 The non-monetised benefits which are important to the users have been identified as including:

- The use of proportionate, risk informed regulation, will provide confidence to users and society in general.

- There will be harmonisation with other national and international legislation and standards. This may have a positive effect on matters such as international trade.

- The new regime responds positively to stakeholder demands for a revised exemptions regime which is flexible and transparent in its derivation. Thus increasing the confidence of users in the regulatory process.

- Relegation of as much detail as possible from the statutory instrument to guidance provides a measure of future proofing which will make the regime easier to amend in the future and reduce policy development costs in the future.

- The proposals will introduce a simpler system which will create an environment that is more conducive to new business start up.

3. Sensitivity of net benefits of Option 2 to key assumptions

3.1 Net benefits under both options are sensitive to assumptions. Three key assumptions are:

- The number of new users entering the regime annually relative to existing users in 2011
- The time savings for new users for familiarisation to the EO regime as a result of changing the regime, relative to the time required for existing users to familiarise themselves with the new regime.
- costs/benefits to regulators.

3.2 Below, we have examined the sensitivity of net benefits of Option 2 to changing the central assumptions made.

Number of new users entering the regime annually

3.3 To examine the sensitivity of net benefits to the number of new users entering the regime annually, we hold the number of existing users in 2011 constant at 22,000, we hold the time required for existing users to familiarise themselves with the new regime at 0.1 days, hold the time savings for new users at 0.5days, we hold the regulators values at their mid points and vary the number of new users entering the regime annually:

Scenario	Low	Central	High
number of new users entering the regime annually	900	1100	1300
NPV (£ 000)	£8,218.4	£8,929.0	£9,639.6

Time savings for new users for familiarisation

3.4 To examine sensitivity of net benefits to the time savings for new users for familiarisation to the EO regime as a result of changing the regime, we hold the number of existing users in 2011 constant at 22,000, we hold the number of new users entering the regime annually at 1100, we hold the time required for existing users to familiarise themselves with the new regime at 0.1 days, we hold the regulators values at their mid points and vary the time savings for new users:

Scenario	Low	Central	High
time savings for new users for familiarisation to the EO regime as a result of changing the regime	0.25 days	0.5 days	0.75 days
NPV (£ 000)	£6,974.8	£8,929.0	£10,883.2

Costs / benefits to regulators

3.5 To examine the sensitivity of net benefits to the cost of regulators time, we hold the number of regulators in 2011 constant at 100, we hold the cost (£000) required per regulator to familiarise themselves with the new regime at 1.6, hold the time savings for regulators at 4 days/year, we hold the users values at their mid points and vary the cost of regulators time:

Scenario	Low	Central	High
Regulator time in £/day	750	1100	1500
NPV (£ 000)	£6,939.3	£8,929.0	£11,203.0

Summary of sensitivity results

3.6 The most pessimistic set of assumptions above are provided from 750 regulator cost/day results in net benefits (NPV) of £6,939.32K (all other values are centrally set).

3.7 The most optimistic set of assumptions above are provided from £1500 regulator cost/day results in net benefits (NPV) of £11,203.0K (all other values are centrally set).

4. Specific Impact Checklist

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

Competition Assessment

4.2 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

4.3 The proposals are not anticipated to negatively affect small businesses, their customers or competitors. Indeed any proposal which reduces administrative burden should help small firms 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 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

4.4 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

4.5 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

4.6 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

4.7 It is not considered there will be significant effects on emissions of greenhouse gases as a result of the implementation of this policy. Therefore, a full carbon assessment is not appropriate.

Equality Assessment

4.8 It is not expected that the proposals will have an impact, negative or positive, on any of the equality target groups (race, disability or gender).

Human Rights

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

Rural Proofing

4.10 The policy is 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. 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), it could be to review existing policy or there could be a political commitment to review];
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 PIR: [If there is no plan to do a PIR please provide reasons here]

Options Development

This Annex outlines the development of the options from the [the original options assessment carried out in 2006, through] to the options under consideration in this Impact Assessment.

Options considered in the options assessment

Experts from Government, the environmental regulators and persons currently holding permits under RSA93 competitively considered the merits and disadvantages of each of the options to provide an overall preferred option.

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>

Option 1 - Do Nothing (Option 0 in this impact assessment)

The suite of EOs would remain the same; unstructured and outdated, not meeting current or future needs.

Option 2 - Minor Updates (Option 1 in this impact assessment)

All current EOs still required would be revised using clear unambiguous language, SI units, up to date references, a consistent layout across all the EOs including harmonising conditions, checking consistency with other legislation and updating coverage. This would make it simpler for stakeholders to understand the content of the EOs. It would not, however, eradicate the disparities in the structure and philosophy, with each of the EOs having different purposes. No change to the scope of regulation. Supporting guidance would be produced.

Option 3 - Full Updates

This option includes the revisions in option 2 with the additions of a reappraisal of exemption values and the Schedule 1 values of RSA 93. The revision would completely change the

content and structure of the EOs to reflect current and future usage, and would aim to simplify the process for amending EOs in future. Supporting guidance would be produced.

Option 4 - Rebrigading

This option would replace the present suite of 18 EOs with around 6 of a more general nature based on source types. Within each of these more general EOs, there would be a separation into unconditional and conditional exemptions. It would also include a reappraisal of numerical values found in exemptions and Schedule 1 of RSA 93. Supporting guidance would be produced.

Option 5 - Top Level (Option 2 in this impact assessment)

This option would replace the present suite of 18 EOs with two top level EOs, one for unconditional exemptions and one for conditional exemptions. This would set out general arrangements, with the details (numerical values and conditions) located in schedules. It would also include a reappraisal of exemption values found in Schedule 1 of RSA 93 and a change in definition of radioactive materials and wastes. This would involve a significant rationalisation and simplification of the current EO regime and would relegate as much detail as possible to supporting guidance. **Option 6 - Goal Setting/Dose Based Approach**

The model for this option is the statutory instrument 'The Justification of Practices Involving Ionising Radiation Regulations 2004' (S.I No 2004/1769) which sets out what needs to be done to make an application for a justified practice and how such an application is determined. Justified practices are kept on a public register in accordance with the Regulations. This option would work in a similar way for exemptions from registration and authorisation. The exemptions register would be built up from two sources – an initial list (based on as assessment of currently exempt practices) and subsequent applications. Applications would be made to the Secretary of State (or regulator if the decision making power could be delegated). Decisions on exemptions would be taken by the Secretary of State. In practice, recommendations based on technical assessments (dose based approach), would be made to the Secretary of State by officials and environmental regulators who could constitute a technical assessment panel. Supporting guidance would be produced.

Options assessment outcome

Whilst Options 3, 4 and 5 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 was that there should only be one exemption order and not two. In summary it was considered that:

- it was the most compatible with other better regulation initiatives such as the Environmental permitting regime and other environmental protection legislation;

- it was very adaptable to new circumstances and practices;

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

- it would be risk-informed.

Preferred Option development process

Following a stakeholder engagement workshop in Cardiff (January 2007) and an expert elicitation workshop in Reading (July 2007), the six options for the framework of the proposed exemptions regime (set out in Table 1) were developed and underwent a thorough options assessment which involved extensive engagement with experts from Government, the environmental regulators and persons currently holding permits under RSA93.

Following the option assessment process detailed work was undertaken to populate the preferred EO framework (Option 5) with numerical values and conditions. A workshop was held to test the inputs to the proposed new framework and the general principles were accepted by stakeholders.

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.

A further pre-consultation stakeholder workshop was held in May 2009 which led onto a full public consultation exercise from June to September 2009.

Public Consultation 2009

A link for further information on the public consultation material (based on a developed Option 5) can be found here.

In general the regulatory framework as proposed in the consultation was accepted by most consultees. The proposals retain the overall philosophy, whereby it is accepted that nearly all materials and wastes are radioactive (the exception being certain materials such as 'pure' manufactured items in which any radioactivity has been chemically removed). They place all materials and wastes into one of three categories:

- Outside the scope of regulation; that is, not defined as radioactive for the purposes of regulation.
- Within the scope of regulation, but conditionally exempted from the need for prior permitting by reason of low risk.

1.

- Within the scope of regulation, and requiring prior permitting and full regulation by the environmental regulators.

Main issues raised by consultees

The main issues raised during the consultation, and addressed in revised proposals, are:

- How to account for background activity in determining whether or not radioactive substances or articles are outside the scope of regulation.
- How to remove from the scope of regulation certain activities dealing with naturally occurring radioactive materials and wastes (NORM).
- How to provide an appropriate replacement for the Substances of Low Activity Exemption Order.
- How to provide appropriate levels to remove aqueous liquids and gases from the scope of regulation or alternatively exempt them.
- How to avoid 'double regulation' of permitted waste disposals.
- How to include provisions for non-aqueous liquids.

2.

- How to provide adequate replacement of the Phosphatic Substances, Rare Earths Exemption Order to allow disposals of higher volume NORM wastes.

- How to adequately incorporate specific provisions for holdings of sealed sources and other items, and waste disposal of these items, as covered by the current exemptions regime.

3.

- Consideration of applying different concentration limits for exempting 'wet sludges' (RP122 Part 2) and recycling building rubble and scrap metal (RP113 and 89).

Consultation outcome and development of firm proposals

The changes proposed are modifications to details, with expansion of some of the provisions (an important case in point being the extension of the exemptions regime to deal with NORM wastes in significant volumes). The revisions have been based on recommendations from an expert group comprising technical experts from Government, the environmental regulators, the Health Protection Agency, and external consultants. The work of this group has been 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 have been developed around these key changes/issues and will be tested with further stakeholder engagement.

Option 2 summary – Top level rationalisation and simplification of Existing Regime

1. 18 existing exemption orders are consolidated into one statutory instrument in England and Wales (EPR10 Schedule 23) and one in Scotland and Northern Ireland (Exemption under RSA93). The effects under both pieces of legislation are identical.

2. The exemptions regime is based to a large extent on the Basic Safety Standards Directive 1996 (BSSD), which exempts certain matters from the need for 'prior reporting'. Some of these matters, relating to concentrations and holdings of radioactive material, are set out in the Directive. But the Directive allows Member States to have, in national legislation, other exemptions for specific circumstances provided that the relevant standards of radiation protection are met.

3. The exemption order provisions dovetail with new proposals relating to the scope of radioactive substances legislation (RSA93, EPR10); that is, matters which are not deemed radioactive for the purposes of the legislation. 'Out of scope' and 'exemption' are closely related concepts, and it is important that the two sets of proposalsare taken as a whole when a user is deciding how the regulatory regime applies to any specific situation.

4. Existing exemption orders are a mixture of conditional and unconditional exemptions. The proposed new order is a conditional exemption.

5. The proposed new order is divided into sections, one section relating to each of:

- Exemption for 'keeping and use'.
- Exemption for 'keeping and use' (mobile sources).
- Exemption for waste disposal (solids)
- Exemption for waste disposal (liquids)
- Exemption for waste disposal (gases).
- Exemption for waste disposal (solid NORM wastes arising from work activities).
- Exemption for radioactive materials or wastes stored in the course of a journey ('storage in transit')).

6. Each exemptions section is followed by the conditions which apply to that type of exemption. The conditions are put in place to ensure that the radiological dose limits will be met and that satisfactory controls are in place for those persons having responsibilities for the management of radioactive materials and wastes.

7. 'Keeping and use' provisions, for both fixed and mobile sealed sources, and for open source material, are set out in a Table , copied directly from Annex 1 of BSSD.

8. Additional exemptions for keeping and use, for specific circumstances, source types, and uses, are set out in another table. These additional exemptions are based on historical exemptions applying in the UK where the UK Government could be satisfied that the radiological dose limits would be complied with without the need for permitting.

9. Exemptions for waste disposals (solids) are based on the UK Government's Low Level Radioactive Waste Policy 2007, which defines Very Low Level Radioactive Waste (VLLW) in terms of activity concentration. VLLW is exempt from the need for permitting

up to certain volume limits. These limits have been derived from HPA radiological impact assessment studies.

10. Exemptions for waste disposals (liquids) have been derived based on Health Protection Agency (HPA) radiological impact studies. Exemptions apply to aqueous liquid wastes up to certain radionuclide concentrations.

11. Exemptions for gaseous disposals are qualitative, but are based on BSSD Annex 1 values for solids. They are intended for small-scale disposals from, say, laboratory procedures.

12. Additional waste exemptions apply to higher volume wastes comprising naturally-occurring radioactive materials (NORM) generally arising from industrial activities.

13. To avoid double-regulation, a further exemption, with relevant conditions, applies to radioactive materials and radioactive wastes stored in the course of a journey. Regulation in these cases is a matter for Department for Transport (DfT), where Transport Regulations themselves exempt the need for full regulation.

14. Finally, the proposed new exemption order tidies up matters which have in the past been the subject of difficulties of interpretation, and rendered the exemption provisions into the language of modern legislation. Of particular note, attention has been given to:

    - Activity units, which are now based on international standards applied from 1985.

    - Removal of industry-specific exemptions, which rely on definitions of such things as ‘school’ or ‘hospital’.

    - A consistent approach to all exemptions, removing the apparent discrepancies between the current 18 orders.

15. The proposed exemptions regime is 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 exemptions provisions. This guidance will be followed by more detailed guidance prepared by the regulators.

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