EXECUTIVE NOTE

THE RADIOACTIVE SUBSTANCES ACT 1993 AMENDMENT (SCOTLAND) REGULATIONS 2011

SSI 2011/207

1. The above Instrument is proposed to be made in exercise of the powers conferred by section 2(2) of the European Communities Act 1972. The Instrument is subject to affirmative resolution procedure.

2. The instrument implements one part of review of the exemptions regime for radioactive substances in the UK. The remaining part of the review, the Exemption Order, is subject to negative Parliamentary procedure and is being taken forward separately.

POLICY OBJECTIVES

3. The Scottish Government has reviewed the regime for exempting radioactive materials and radioactive waste from the need for registration and authorisation under Radioactive Substances Act 1993 (RSA93). The review, part of a UK-wide project, was undertaken to: reduce the regulatory burden for radioactive substances that are either ubiquitous or present low risk; respond to stakeholder views that the regime was outdated and difficult to follow and demonstrate clearer compliance with the Euratom Basic Safety Standards Directive (96/29/Euratom) (BSSD).

4. The review, which initially focussed solely on the suite of Exemption Orders issued under RSA93, was widened to include the definitions of radioactive material and radioactive waste. This was done when it became clear that a logical, comprehensive and modern regime could only be delivered if these definitions were amended. The definitions had existed in their current form since they were first defined in the Radioactive Substances Act 1960.

5. In rewriting the definitions of radioactive material and radioactive waste, the requirements of the BSSD and guidance issued by the European Commission were taken into account. Naturally occurring radioactive substances (referred to as NORM) are excluded from regulation where, for specified industrial activities, the radioactive concentrations are below levels derived from a radiation dose constraint of 300 microsieverts per year. For man made radioactive substances and naturally occurring radioactive substances used for their radioactive, fissile or fertile properties, the dose constraint upon which exclusion concentrations are based is 10 microsieverts per year. These dose constraints are taken from guidance issued by the European Commission. Further exclusions are made for substances that are either impracticable to control e.g. very low levels of man-made contamination distributed widely in the environment due to climatic processes; or where it is not considered desirable to control e.g. substances contaminated by previously authorised radioactive discharges.

6. The Scottish Government will be issuing guidance to the Scottish Environment Protection Agency to set out the intent of the legislation.

7. The review includes changes to the suite of exemption orders, with the current 18 orders being revoked and replaced by a new single order. Exemption orders remove the need for certain low risk activities to be registered or authorised by the Scottish Environment Protection Agency.

Exempt activities will remain subject to conditions and limitations which ensure that the public and environment continue to be protected.

CONSULTATION

8. 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 non-nuclear industry, nuclear industry, interested groups and individuals.

9. 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 had undergone substantial change. In view of this Government held a further round of stakeholder engagement in 2010 and this has now led to the draft regulations submitted to the Scottish Parliament.

EFFECT OF THE REGULATIONS

10. The Regulations will amend sections 1 and 2 of the Radioactive Substances Act 1993, changing the definitions of radioactive material and radioactive waste.

11. The exemptions for clocks and watches provided in sections 8(4) and 15(1) are repealed and new provisions will be included in the new Exemption Order.

12. A minor amendment is made to section 15(2) to rectify a long standing error where the terms ‘exclude’ and ‘exclusion’ were used instead of ‘exempt’ and ‘exemption’.

13. Amendments are made to Sections 47 and 48 to include some new or updated definitions.

14. Schedule 1 is replaced by Schedule 1A. Schedule 1A has four tables listing: NORM industrial activities to which the Act applies; the concentrations above which substances or articles are considered to be radioactive material or waste; and the radioactive decay products which have been taken into account when setting these concentrations.

FINANCIAL IMPLICATIONS

11. The attached Business and Regulatory Impact Assessment demonstrates that the amended regulations will be financially beneficial to users and regulators. The assessment is based upon the effect of the changes to the exemption regime, that is both the regulations and the exemption order.

12. The simplified exemption regime will reduce the time spent by users of radioactive substances interpreting and implementing the legislation. It will similarly reduce regulatory effort in this area. It is estimated that these savings will recoup the costs of implementing the new regime within five years.

Radioactive Waste Team
Scottish Government
March 2011

Business and Regulatory Impact Assessment

The Radioactive Substances Act 1993
Amendment (Scotland) Regulations 2011

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1. Introduction

1.1 The Radioactive Substances Act 1993 Amendment (Scotland) Regulations 2011

1.2 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.

1.3 Responsibility for the subject matter of the RSA93 lies with the Scottish Government and it is administered by Scottish Environment Protection Agency (SEPA). The regime is mirrored across the UK leading to a consistent UK-wide approach to the regulation of radioactive substances.

1.4 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 regulatory system in Scotland and the rest of the UK. There has been extensive stakeholder engagement during the development of these proposals including inter-Governmental meetings, stakeholder workshops, meetings with targeted industries, 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 favourable recognition from stakeholders.

1.5 The changes proposed will be implemented by the Radioactive Substances Act 1993 Amendment (Scotland) Regulations 2011 together with a new single Exemption Order (with 18 existing ones revoked). The 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 Exemption Order (EO) will considerably simplify the often complex system for users of radioactive substances that present very low risk to people or the environment.

2. Purpose and intended effect of the proposals

Objectives

2.1 The aim of the proposal is to simplify regulation, reducing the regulatory burden on industry through an improvement in legislation. The EO review, which is re-evaluating the scope of regulation and exemption from some of Radioactive Substances Act 1993 (RSA93) provisions, is being undertaken across the UK. It introduces 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 Scotland and the rest of 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 The key success criteria outlined at the start of the programme were:

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

2.3 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

2.4 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 concentrations 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. Exemption Orders (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.

2.5 The first Radioactive Substances Act (RSA60) 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 18 EOs have now been added to the regime.

2.6 In essence very little has changed in terms of the legislation since the early 1960s. 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

2.7 The rationale for reviewing the current exemption orders regime are threefold:

- reducing regulatory burdens;
- responding to stakeholder views that an EO review is long overdue; and
- to demonstrate clearer compliance with the EU Basic Safety Standards Directive (96/29/EURATOM) (BSSD).

2.8 The regulatory landscape has changed since the RSA60 was first introduced (RSA93 did not make substantive changes to how the regime operated) with greater emphasis on a graded or proportionate 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.

2.9 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.

2.10 A wholesale review of EOs 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. 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, 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.

2.11 The aims of this review will further the National Performance Framework Purpose 'to rank in the top quartile for productivity against our key trading partners in the OECD by 2017' by cutting the amount of time users and regulators spend on regulation.

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, non-nuclear industry and other interested groups or individuals.

3.2 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 had undergone substantial change. In view of this Government held a further round of stakeholder engagement in 2010 and this has led to the agreed draft regulations, which will be laid in the Scottish Parliament in January 2011.

Within Government

3.3 The consultation took into account the recommendations of Government departments and agencies across the UK, such as the Government Decontamination Service, the Nuclear Decommissioning Authority and the Health and Safety Executive. In Scotland, this included SEPA, the local authorities and the Lothian Health Board.

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 who used the current system, professional and academic associations, industrial institutions and international oversight bodies.

Business

3.5 The UK-wide consultation process took Scottish firms into account. These included international energy companies with significant operations in Scotland, Scottish- based manufacturing companies and supply chain companies to the energy sector. The financial implications of the regulations are also relevant to hospitals who use radioactive material in medical treatment, and schools and universities who use radioactive material for teaching and research.

4. Options

4.1 Following a stakeholder engagement workshops 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 Scottish Environment Protection Agency (SEPA) 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 EOs with all the detail in the 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 six options against five agreed attributes and their conclusions are summarised in Table 1.

Table 1

Attributes	1	2	3	4	5	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

4.3 Following the option assessment process detailed work was undertaken to populate the preferred EO 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 further pre-consultation stakeholder workshop was held in May 2009 which led onto a full public consultation exercise from June to September 2009.

4.5 In view of the extensive engagement used in the selection and development of Option 5, the subsequent public consultation and further round of stakeholder engagement in 2010, these six options have not been considered in this assessment. Rather it is only considered appropriate to consider the two broad options available at this stage:

Option 1 – Do nothing

Option 5 – Preferred option (top level rationalisation and simplification of the existing regime)

Sectors and groups affected

4.6 The Exemptions Regime covers a broad range of users, including hospitals, universities, schools manufacturers (e.g. smoke alarms and electronic valves), the oil and gas industry and the nuclear industry.

4.7 The nature of the Exemptions Regime is that the majority of users do not need to be aware of it; that is, only those for whom exemption from regulation is conditional need to apply for a permit registering their exempt status. The majority of users will therefore be unaffected.

4.8 Affected users will be affected by the new regime in that they will be able to establish whether they are exempt more easily, thereby cutting the administrative costs incurred by regulation. This will also reduce the necessity to pay Radiation Protection Advisers (RPAs) for professional advice. These benefits will be delayed by the time taken for users and RPAs to familiarise themselves with the new regime and, in some cases, the cost of producing new internal guidance.

4.9 SEPA will be affected by the new regime as regulation which is simpler to understand will translate into less time handling calls concerning the regime. This benefit will be delayed by the time taken for regulators to familiarise themselves with the new regime and produce new guidance for users.

Costs and Benefits

4.6 The cost and benefit estimation for the review of the exemptions regime is difficult for two reasons:

(i) We do not know (almost by definition) how many users of radioactive substances are currently employing the exemptions regime. This is because EOs are 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, respondents were unable to quantify the costs and benefits. This was also the case in the further 2010 stakeholder engagement exercise.

4.7 The main monetary costs and benefits of Option 5 relative to 'do nothing' are:

One-off transition costs:

- One-off transition costs of familiarisation to the proposed regime for existing EO users;
- One-off transition costs of familiarisation to the proposed regime for Regulators
- One-off transition costs of familiarisation to the proposed regime for Radiation Protection Advisors (RPA)
- One-off costs for producing Regulators procedural guidance for industry
- One-off costs for producing internally produced procedural guidance for industry

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

Assumptions

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

(i) SEPA believe that there is an estimated total user pool of 4050 using the exemptions regime in Scotland. This is based on there being currently 810 permits in use in Scotland, and that, on average, a permit holder has 2 permits totalling the current number of permit holders at 405. They believe that there are at least 10 EO users for every permit holder giving the total user pool. This is probably a reasonable order of magnitude estimate but clearly subject to uncertainty for the reason given above.

(ii) It is estimated that around 800 new users per year would use the exemptions regime. This figure is sourced from information presented by SEPA based on an average of 80 new permits issued per year over the past 5 years and an assumption of 10 EO users for every permit holder. The number of users entering and exiting the regime will be similar so the overall population will remain neutral.

(iii) 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 4050 users, 385 have been highlighted as extensive users, 2865 have been highlighted as non-extensive users and 800 have been highlighted as new users. This has been based on advice from stakeholders within the nuclear & non-nuclear industries (including SEPA). This is probably a reasonable order of magnitude estimate.

(iv) The daily cost of professional advice required by a user for familiarisation with the EO is £750. There are around 55 Radiological Protection Advisers (RPAs) in the Scotland. This is based on advice from the Society of Radiological Protection (an UK organisation of professional radiation specialists) on the average consultancy rate of RPAs (which range from £500 to £1500).

(v) The daily cost for SEPA for exemption related work is £850. SEPA has around 10 Radioactive Substances Regulation (RSR) Regulators responsible for EOs. Regulators

costs range from £700/day for non-nuclear regulators to £1500/day for nuclear regulators so an average of £850/day has been selected as an appropriate figure (as most users are from the non-nuclear industry). This is based on advice from SEPA.

(vi) Although SEPA 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 the BRIA, it has been assumed that the number of permits will remain the same.

(vii) It is anticipated that waste management costs will decrease under the new exemptions regime. Although some users will have higher waste management costs, others will see waste management costs decrease, and hence for the purposes of this BRIA, it is assumed that the overall waste management costs will not change.

(viii) The new regime will last for perpetuity but the Net Present Value (NPV) calculation is based on 10 years.

Option 1 - Do Nothing

4.9 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.

4.10 The economic benefit of Option 1 is that there will be no initial outlay for users, RPAs or regulators to familiarise themselves with the new Regime and no need for users and regulators to produce guidance on the regime. The estimated one-off cost of £1 395 000 would not therefore be incurred (see 4.13 – 4.14).

4.11 The cost of Option 1 would be to fail to make the regulation more efficient. It is estimated that not creating these efficiencies will come at a net cost to users of £1 280 000 over ten years (see 4.15 – 4.19).

Option 5 - The revised Exemptions Regime - Top Level Rationalisation and Simplification of Existing Regime

Option Summary

4.12 The revised exemptions regime replaces the present suite of 18 EOs (including amendments) with one top level EO for conditional exemption. This sets out the general arrangements with the detailed revised numerical values located in schedules. This involves a significant rationalisation and simplification of the current regime and relegates as much detail as possible to supporting guidance to provide some flexibility in and future amendments. It also provides a measure of future-proofing through moving from a industry/activity specific based set of regulations to a more generic, radionuclide based set of regulations. The revised regime also includes 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.

Costs

4.13 The one off costs to users is estimated to be in the region of £1 406 000. This is based on:

- £647 000 cost of users familiarising themselves with the new regime, involving 385 extensive users spending 3 days at a cost of £250/day and 2865 spending 0.5 days at the same rate.

- £206 000 cost of RPAs familiarising themselves and providing advice on the new regime, involving 55 advisors spending 5 days at a cost of £750/day.
- £553 000 cost of users producing new internal guidance, involving 385 extensive users spending 5 days at a cost of £250/day and 2865 non extensive users spending 0.1 days at the same rate.

The amount of time estimated to be spent on familiarisation and guidance by non-extensive users is largely nominal.

4.14 The one-off costs to regulators is estimated to be in the region of £39 000. This is based on:

- £6 000 cost of developing regulatory guidance covering the new exemptions regime involving 5 working days at £1100/day.
- £33 000 cost of regulators updating themselves with the new regime is estimated at 3 working days/regulator across 10 regulators at the above rate.

Total one-off cost of £1 444 000 discounted to £1 395 000.

Benefits

4.15 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 advice through their RPAs. We believe that, in theory, users should not need to seek specialist help at all, although in practice this may not be the case.

4.16 Ongoing benefits to RPAs are estimated to be in the region of £41 000 per annum. This is based on a reduction of 1 day/year spent on advising on EOs for 55 RPAs at a cost of £750/day.

4.17 Ongoing benefits to all users are estimated to be in the region of £187 000 per annum. This is based on a reduction in EO use due to simplification of 1 day/year for 385 extensive users at £250/day and 0.1 day/year for 3645 non extensive users at the same rate.

4.18 Ongoing benefits to new users are estimated to be in the region of £68 000 per annum. This is based on an assumed reduction in the required familiarisation time, relative to "do-nothing", for each EO user to familiarise themselves with the regime of 2 days for 40 extensive new users at a cost of £250/day and a reduction of 0.25 days for 760 non-extensive new users at the same rate.[1]

4.19 Ongoing benefits to regulators are estimated to be in the region of £25 500 per annum, based on forecasts estimated by SEPA on a reduced time for 10 regulators of 3 days/year spent dealing with EO queries due to the detailed guidance and revised, simplified regime.

The present value of these benefits is £322 000.

Net Benefit over 10 years £1 280 000.

[1] Where 800 new users are assumed based on an average of 80 new permits issued per year over the past five years and 10 users are assumed per permit.

4.20 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.

5. Scottish Firms Impact Test

5.1 This engagement was carried out on the assumption that a UK-wide impact assessment would be sufficient. The Scottish Government has not therefore carried out a separate consultation with six to twelve Scottish firms in addition to the other forms of engagement and assessments. However, an extensive consultation process has been jointly carried out with UK Government and an economic impact assessment produced for Scotland.

5.2 Scottish Firms participated in the UK-wide consultation process. These included international energy companies with significant operations in Scotland, Scottish-based manufacturing companies and supply chain companies to the energy sector. The implications of the regulations are also relevant to hospitals who use radioactive material in medical treatment, and schools and universities who use radioactive material for teaching and research.

5.3 Representatives of Scottish businesses were present at all stages of the UK-wide stakeholder engagement, including the initial discussions when options were discussed and the preferred option was chosen for development, the formal consultation and the follow-up period of engagement.

Consultation Responses and Financial Impact

5.4 The formal consultation showed overall support for the new regime, and general contentment with the conditions set out in the draft regulations. However, concerns over the numerical values and definitions used led government to substantially change the draft.

5.5 Businesses were concerned to ensure regulatory consistency across the UK.

5.6 Businesses believed there would be savings, even ‘significant’ savings, due to the reduced administrative burden. Some Oil and Gas companies were concerned about the familiarisation costs. However, no business could provide meaningful estimates as to either of these predictions at the consultation stage.

5.7 Following the consultation, the economic impact assessment indicates that there will be a total cost to users in the first year of £1 406 000, but over the course of ten years there

will be a net saving to users of £1105 000. The subsequent benefits to users are calculated as being £296 000 per year, so the initial outlay by users will be recovered after five years.

Competition Assessment

5.5 The Department of Energy and Climate Change Impact Assessment of the Review of the Exemption Orders under the Radioactive Substances Act 1993, published in August 2010, included a competition assessment which considered the four questions posed by the Office of Fair Trading. It found that 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.

Test Run of Business Forms

5.6 The exemptions regime alters what substances fall in or out of regulation and does not affect the permitting process. Therefore, because exempt substances and those falling out of the scope of the legislation entirely do not require permitting there will not be any affect upon business forms.

6. Legal Aid Impact Test

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

7. Enforcement, Sanctions and Monitoring

7.1 The proposals do not make any alterations to the current enforcement, sanctions or monitoring regime.

8. Implementation and delivery plan

8.1 The regulations and exemption order will come into force in October 2011. This will be published via the stakeholder network established during the development of the regime. The Scottish Government's and SEPA's websites will also publicise the change.

8.2 There will be a six month transitional period for existing users of radioactive substances to apply for a permit where the new regime requires one. Where exemption conditions change or users find that exemption now applies to them they will also be given six months to comply with the new system.

8.3 Guidance on the Scottish Government's intent behind the legislation will be issued to SEPA but this will also be available publicly for users of radioactive substances. SEPA will also produce procedural guidance for operators.

9. Post implementation review

9.1 The effectiveness of the proposals will be reviewed by the Scottish Government. In view of the UK-wide approach to this project this review is likely to be done in conjunction with the UK Government, Welsh Assembly Government and Northern Ireland Executive over the course of the next five years.

10. Summary of costs

10.1 The economic impact assessment accompanying this document details the costs and benefits of Option 5.

11. Summary and Recommendation

11.1 Table 2 summarises the effects of each option.

Table 2

Option	Effects	Estimated costs
Option 1.	**Positive Effect** • .No initial outlay **Negative effects** • .Continued inefficiencies • Failure to respond to stakeholder requests for an updated system	£0 £1280 000 net loss over ten years. Failure to comply with Better Regulation and continued difficulties for users.
Option 5.	**Positive Effect** • A more relevant system and simplified system • Administrative savings for users and regulators **Negative effects** • One-off costs for Government and users	£1280 000 net benefit over ten years. £322 000 per annum £1 395 000 (discounted)

Recommendation

11.2 After significant stakeholder consultation, option 5 was developed for a formal consultation process. It was developed further in response to this consultation to accommodate the technical issues raised by stakeholders. The changes to the current system will require initial costs for familiarisation and transition for some users, but will simplify the regulatory system and will reduce the administration costs for the regulators and users.

11.3 It is therefore recommended that the Radioactive Substances Act 1993 Amendment (Scotland) Regulations 2011 be implemented in Scotland.

Declaration

I have read the Business and Regulatory 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) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed…….

Date……