EXPLANATORY MEMORANDUM TO

THE HIGH-ACTIVITY SEALED RADIOACTIVE SOURCES AND ORPHAN SOURCES REGULATIONS 2005

2005 No. 2686

1. This explanatory memorandum has been prepared by The Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations contain relevant provisions aimed at preventing exposure to radiation resulting from the inadequate control of high-activity sealed radioactive sources and make amendments to the Radioactive Substances Act 1993. They establish a more detailed and rigorous regime of regulatory control and site security than is currently provided for under existing legislation, for those sources that represent the greatest risk. They also make provisions for detecting, recovering and dealing appropriately with radioactive sources that are not currently under regulatory control (so-called orphan sources).

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

3.1 None.

4. Legislative Background

4.1 These Regulations implement Council Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources. Member States must bring into force measures to comply with this Directive before 31 December 2005. A transposition note is attached to this memorandum at Annex 1.

4.2 High-activity sealed radioactive sources as defined in the Directive are radioactive material for the purposes of the Radioactive Substances Act 1993 and are currently regulated under that Act. These Regulations require those who hold registrations or authorisations in respect of high-activity sources to apply to the regulator for those registrations or authorisations to be amended to include provisions required by the Directive. The Regulations also amend the Act so that it includes additional provisions, as required by the Directive, relating to changes to registrations and authorisations for high-activity sealed sources (HASS). They also include provisions regarding the security of premises on which such sealed sources are held and for dealing with incidents involving orphan sources.

4.3 These Regulations are supplemented by the HASS (England) Directions 2005, addressed to the Environment Agency, which make specific provisions relating to registrations and authorisations under the Radioactive Substances Act 1993. They also provide for matters relating to site security that supplement the requirements of the Directive. Equivalent Directions will be made by the devolved administrations.

5. Extent

5.1 This instrument applies to all of the United Kingdom, except for regulation 5, which applies to England, Wales and Scotland only.

5.2 Council Directive 2003/122/Euratom also applies to Gibraltar, which will make similar Regulations.

6. European Convention on Human Rights

The Minister of State for Environment and Agri-Environment has made the following statement regarding Human Rights:

In my view the provisions of the High-activity Sealed Radioactive Sources and Orphan Sources Regulations are compatible with the Convention rights.

7. Policy background

7.1 In its 14th annual report, the Radioactive Waste Management Advisory Committee (RWMAC) stated that there was a need to assess the risk from lack of positive control of any sealed or unsealed radioactive source. A study carried out by consultants on behalf of Government in 1995 concluded that, although the number of significant incidents involving lost sources in the UK is small and the standards of control generally high, some improvement could be made in the effectiveness of control.

7.2 In participating in the Commission advisory group that made recommendations on the content of the draft Directive on the control of high-activity sealed radioactive sources, the Environment Agency was particularly aware of the potential burdens that might fall on industry in the UK. While these Regulations will place additional burdens on users of high-activity sealed sources and on the regulatory bodies, they will provide enhanced security and increased protection of public health. They will also benefit the metals recycling industry by preventing situations in which sources that have been lost from regulatory control are accidentally smelted with metal scrap.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum at Annex 2.

8.2 The impact on the public sector will include regulatory costs estimated at around £1 million per year. Public sector users of high-activity sealed radioactive sources will bear a part of the total compliance cost estimated at £1.8 million per year. The RIA does not separately identify compliance costs for the public sector.

9. Contact

Dr Martin Hum at the Department for Environment, Food and Rural Affairs Tel: 020 7082 8492 or e-mail: martin.hum@defra.gsi.gov.uk can answer any queries regarding the instrument.

Annex 1: HASS Directive Transposition Note

TABLE SHOWING BY PARALLEL TEXT ANALYSIS HOW ELEMENTS OF COUNCIL DIRECTIVE 2003/122/EURATOM ON THE CONTROL OF HIGH-ACTIVITY SEALED RADIOACTIVE SOURCES AND ORPHAN SOURCES (THE HASS DIRECTIVE) HAVE BEEN IMPLEMENTED BY THE HIGH-ACTIVITY SEALED RADIOACTIVE SOURCES AND ORPHAN SOURCES REGULATIONS 2005 (S.I. 2005/2686)

Provision of Directive	Provision of Regulations	Comment
Article 1: Purpose and scope. Paragraph (2) "This directive applies to high-activity sources as defined in Article 2. Member States may exclude sources from the scope of this Directive once their activity has fallen below the exemption levels specified in Directive 96/29/Euratom".	Regulation 2 (2):	Unless otherwise stated, expressions used that appear in the Radioactive Substances Act 1993 (c.12)(the 1993 Act) or the HASS Directive have the same meanings in the Regulations. Regulation 17 amends the 1993 Act with regard to certain expressions. High-activity sealed sources (HASS) are not subject to these Regulations once their activity has fallen below the exemption levels specified in column 2 of table A of Annex 1 of Directive 96/29/Euratom.
Article 2: Definitions. 2(a) to (n) define expressions used in the Directive.	Regulations 2 and 17 as above.	Definitions in the Regulations comply with those in the HASS Directive
Article 3: Authorisation, Paragraph (1).	No new provision required under these Regulations.	The requirement for holders of high-activity sources to have an authorisation within the meaning of Art.2(d) of the Directive is already covered by registrations and authorisations granted under the 1993 Act.
Article 3: Authorisation, Paragraphs (2) and (3). Member States to ensure before issuing authorisation that adequate arrangements have been made for safe management of HASS. For disused sources, such arrangements are to include adequate financial provision. Member States to ensure that the authorisation covers certain minimum requirements.	Regulations 3 and 4.	Persons who hold a registration or an authorisation under the 1993 Act in respect of a HASS are required to apply to the appropriate environmental regulator to have their registration or authorisation varied so that it complies with the HASS Directive's provisions. Under directions 3 and 4 of the HASS (England) Directions 2005* which will come into force at the same time as these Regulations, the Environment Agency is directed to ensure that relevant applications for, and variations of, registrations and authorisations under the 1993 Act

		comply with these paragraphs of Article 3 of the HASS Directive. These Directions include applications for variation of registrations and authorisations made under regulations 3 and 4. (*Equivalent Directions will be made by the devolved administrations).
Article 4: Transfers Member States shall set up a system to enable them to be adequately informed of individual transfers of sources.	Regulation 14.	This regulation amends section 20 of the 1993 Act (retention and production of site or disposal records) to include records concerning the transfer of sources. Direction 6 of the HASS (England) Directions 2005 requires the Environment Agency to attach limitations and conditions to registrations and authorisations to enable it to be informed of the transfer of sources.
Article 5: Records. Paragraphs (1) and (2) require the holder to keep records of HASS, their location and any transfers and provide them to the competent authority, updated as necessary.	Not under the Regulations.	Directions 3 and 4 of the HASS (England) Directions 2005 require the Environment Agency to attach limitations and conditions to registrations and authorisations such that persons are required to keep records as provided by Article 5(1) and (2).
Article 5: Records. Paragraphs (3) and (4) require the competent authority to keep and update as necessary records of authorised holders and the sources they hold.	Regulation 7(a)(i).	The competent authority must keep records of those matters required by Articles 5(3) and (4) of the HASS Directive.
Article 6: Requirements for holders. The holder must carry out suitable tests; periodically verify the location and condition of HASS; have documented security measures; dispose of disused HASS promptly; check the status of recipients of transferred HASS; and notify the competent authority of loss, theft, unauthorised use and any unplanned exposure of workers or public.	Regulations 7(a)(ii).	The competent authority must keep a record of any notification made to it by a holder under Article 6. Directions 3, 4 and 5 of the HASS (England) Directions 2005 require the Environment Agency to attach limitations and conditions to registrations and authorisations such that persons are required to comply with Article 6.

Article 6: Requirements for holders. Paragraph (c). The holder must ensure that each HASS is subject to adequate documented measures to prevent unauthorised access, loss, theft or damage by fire.	Regulations 5 and 6.	In order to ensure that loss, theft or unauthorised use of high-activity sources (and sealed sources of a similar level of potential hazard to such sources) are avoided, there are additional requirements for inspections in regulation 6. Given that the security of a site is not necessarily concerned with the control of pollution, the powers of the Environment Agency and Scottish Environment Protection Agency are extended in regulation 5.
Article 7: Identification and marking. The manufacturer or supplier must ensure that each source is identified by a unique number and accompanied by written information and photographs relating to the design type.	Not under the Regulations.	Directions 3 and 4 of the HASS (England) Directions 2005 require the Environment Agency to attach limitations and conditions to registrations and authorisations such that persons are required to keep records as provided by Article 7(1) and (2).
Article 8: Training and information. The holder must ensure that staff training and information covers safe management of sources and possible consequences of loss of control.	Regulation 19.	The training and information required by regulation 14 of the Ionising Radiations Regulations 1999 and the Ionising Radiations Regulations (Northern Ireland) 2000 must cover sealed sources, as specified in Article 8.
Article 9: Orphan sources. Paragraph (1). Member States must ensure that competent authorities have arrangements in place to deal with orphan source incidents	Regulation 16.	The new s30A(1) of the 1993 Act requires the appropriate agency to put plans in place for dealing with orphan source incidents.
Article 9: Orphan sources. Paragraph (2). Member States to ensure technical advice and assistance is promptly available in suspected orphan source incidents.	Regulation 8.	Requires the “relevant person” (for England and Wales the Secretary of State) to ensure specialised technical advice and assistance are promptly available. Currently, such advice and assistance are provided on a voluntary basis by participants in the National Arrangements for Incidents Involving Radioactivity (NAIR) scheme. Defra is to set up a stakeholder group to put in place a coordinated response system for orphan source incidents.

Article 10: Financial security for orphan sources. Member States to ensure a system is in place to fund the recovery of orphan sources.	Regulation 16.	The new section 30A(2) to (6) of the 1993 Act enables the appropriate agency and the Chief Inspector to recover costs from the source holder or the owner/occupier of the premises, and provides for central Government to fund the recovery and disposal costs if these exceed the agency's reasonable provision.
Article 12: Inspections. Member States to establish a system of inspections	Regulation 7(b).	Requires the appropriate agency to establish or maintain a system of inspections to enforce relevant provisions of the HASS Directive
Article 15: Penalties. Member States to determine penalties, which are to be effective, proportionate and dissuasive.	No new provision required under these Regulations.	The existing penalties under the 1993 Act apply.
Article 16: Transposition. Member States to bring legislation into force before 31/12/05. For HASS placed on the market before 31/12/05, Articles 3 & 6 need not apply until 31/12/07 and Article 7 does not apply until that date and in a modified form concerning information and hazard marking requirements.	Regulations 2, 3 and 4.	High-activity sources already placed on the market before 31 December 2005 are defined in regulation 2 as existing high-activity sources. The requirements for variation of existing registrations and authorisations under regulations 3 and 4 only apply to existing high-activity sources on and from 1 January 2008. These Regulations will come into force on xx October 2005.

Annex 2: Final Regulatory Impact Assessment

1. Title of Proposal

High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005

2. Purpose and intended effect of measure

(i) The objective

Council Directive 2003/122/Euratom on the control of high activity sealed radioactive sources and orphan sources (the HASS Directive) is designed to prevent exposure to radiation arising from the inadequate control of high activity sealed sources. It requires Member States to maintain a regulatory system that involves prior authorisation, control over transfers, and record keeping by holders and competent authorities. It also requires Member States to lay down certain obligations on holders (eg training) and manufacturers (identification and marking). Member States must also ensure that arrangements are in place for recovering "orphan sources" (sources not under regulatory control).

For the purposes of the Directive, a high activity sealed source (HASS) means a sealed source containing a radionuclide whose activity at the time of fabrication or first placing on the market is equal to or exceeds the relevant activity level specified in Annex 1 of the Directive.

Many of the requirements of the HASS Directive are already incorporated into UK legislation, principally via the Radioactive Substances Act 1993, the Nuclear Installations Act 1965 and the Ionising Radiations Regulations 1999. However, some requirements are not fulfilled by existing legislation. The Directive is being transposed by means of Regulations (High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005) made under the European Communities Act 1972 and Directions to regulators made under Section 23 of the Radioactive Substances Act 1993.

(ii) The background

A large number of incidents involving the loss of control of sealed radioactive sources have been reported worldwide over the last 50 years. Some of these incidents have resulted in excessive radiation exposure of members of the public, leading to death or serious injury. In other cases, lost sources have found their way into metal scrap destined for recycling, resulting in widespread environmental contamination requiring costly remediation (Annex A).

There are a number of ways in which a sealed source may become lost, either permanently or reappearing in some way to present a potential hazard to man (Annex B). The most likely reasons for loss are:

- detachment from the original equipment or loss of identification label;
- redundancy of industrial plant and incorporation of source in scrap;
- theft of the source or the equipment that contains the source;
- bankruptcy of the source user;
- intentional discarding of the source in order to reduce the owner's liability;
- unintentional loss of the source.

A proportion of the sealed sources that have been lost and not subsequently recovered will be later intercepted by workers or members of the public, leading to inadvertent radiation exposure. The likely reasons for radiation exposure are:

- handling of the source;
- accidental or intentional damage of the source;
- smelting (or other processing) of scrap metal containing the source, which may lead to widespread contamination.

The current legislative framework for the control of sealed radioactive sources is based on the requirements for registration under Sections 6 or 9 of the Radioactive Substances Act 1993 (RSA93), authorisation under sections 13 or 14 of the Act and prior notification under Regulation 6 of the Ionising Radiations Regulations 1999 (IRR99). Under existing legislation, holders of radioactive sources are required to keep records, carry out regular leakage tests and generally safeguard all such sources. Although existing legislation ensures basic protection, high activity sources still imply considerable risks for human health and for the environment, and therefore need to be subject to a strict control from the moment they are manufactured to the moment they are consigned for long-term storage or disposal.

(iii) Risk assessment

The information required to assess the probability and consequences of each of the above scenarios is not readily available and it is therefore necessary to adopt a simplified approach based on conservative estimates of the parameters involved, derived from historical evidence (Annex B).

It is conservatively assumed that three HASS sources are lost every 10 years in the UK and not recovered. It is further assumed that 10% of those lost sources are later intercepted by man, leading to excessive radiation exposure of the person(s) finding the source, resulting in an assumed single death or serious injury. This represents one serious accident approximately every 30 years, which is consistent with UK experience.

It is similarly assumed that three HASS sources every 10 years find their way into scrap metal, which is subsequently processed or smelted. Historical evidence suggests that an average cost of £7 million would be the appropriate total economic cost for each such event.

It is assumed that the remaining lost sources remain in the environment, do not come into contact with man and undergo radioactive decay, with no significant radiation dose to man. It is likely that the risk will decrease with time due to the legacy of sources lost in an era when control was less rigorous than at present.

3. Options

The Directive must be implemented in the UK by 31 December 2005. The option of non-implementation, which would lead to infraction proceedings and ultimately fines under the Euratom Treaty, is not considered further here.

Reference below to legislation implementing the Directive is to both the proposed Regulations and the supplemental Directions which will be made under section 23 of RSA93.

4. Benefits

The business sectors likely to be most affected by the proposal are the suppliers of HASS sources and the organisations using the sources in medicine, research and industry (see Section 6 below). The categories of individuals and organisations likely to benefit from the legislation are members of the public exposed to radiation arising from a lost source accident and the metals recycling industry affected by the inadvertent smelting of a lost source.

The underlying assumption of the transposing legislation is that the potential for the loss of control of HASS sources would be essentially eliminated under the proposed regulatory regime.

The benefits of the legislation will be the annual costs averted by the reduction in risk associated with the consequences of the loss of control of HASS sources. These "direct" benefits are likely to be health benefits to members of the public and economic benefits to the metals recycling industry (see Section 2(iii) above). Other "indirect" benefits to industry and members of the public have been identified.

- **Economic benefits**

On the basis of 3 serious contamination incidents every 10 years (0.3 per annum), the average annual economic cost of such an incident would be about £2.1 million [Annex B]. However, public aversion to such incidents might lead to higher consequent economic losses, for instance the closure of a business.

In addition to the above "direct benefits", it is likely that significant "indirect benefits", such as improved efficiency, better security and accountability, a safer workplace and improved customer satisfaction, will result from the introduction of the proposed legislation. It was not possible to evaluate such indirect benefits.

- **Environmental and health benefits**

To the extent that the transposing legislation will result in the potential saving of several lives (or serious injuries), an indicative value of life of approximately £1.6 million per life would be appropriate for a cost-benefit comparison [Annex B]. On

the basis of one serious accident every 30 years (0.03 per annum), the average annual economic cost averted would be about £50,000 per annum.

- **Social benefits**

The introduction of the proposed legislation will lead to greater public confidence in the use of radioactive sources. It was not possible to evaluate this factor.

- **Total benefits**

The total benefits, in terms of the averted economic cost resulting from the loss of control of HASS sources, will be an estimated £2.2 million per year (see summary table below and overall summary in Section 12). These benefits are based on historic evidence and are subject to large uncertainty.

Category of benefit	Benefit per annum
Economic	£2.1 million
Environmental	£0.05 million
Social	Not evaluated
Total	**£2.2 million**

5. Costs

The costs of complying with the proposed legislation are likely to be borne by the suppliers and users of HASS sources, the relevant regulatory bodies and also the installations where "orphan sources" are most likely to be found or inadvertently processed.

- **Economic costs**

Information on compliance costs was sought as part of the consultation exercise (summarised in Section 11 below).

For the suppliers and users (i.e. holders) of HASS sources, the cost of compliance with the proposed legislation will include the cost of registration, additional record keeping, reporting, supervision and training. For the manufacturer of sources, compliance will also include supplying relevant information concerning the source identity (assuming that such sources are already adequately marked). Manufacturers are already required to supply relevant information under the Health and Safety at Work etc. Act 1974 (Section 6), so there should not be any significant additional costs.

In the case of HASS suppliers and users, the estimated cost of additional training and administration varied widely but will be typically £10,000 per annum for each company or organisation. With a total of about 180 relevant organisations, the total compliance costs will be about £1.8 million per annum.

For installations where "orphan sources" are most likely to be found or processed (metals recycling plants and ports), the compliance costs will include training in the visual detection of such sources and in the actions to be taken in the event of the detection of such sources. Radiation detection equipment is currently employed at a number of metals recycling plants but the provision of such equipment is not a requirement of the Directive. In the case of the metals recycling industry, the cost of additional training will be typically £200 per annum for each scrap yard or scrap processing company. With a total of about 2,000 scrap yards in the UK, the total cost will be about £0.4 million per annum.

Currently, the storage/disposal cost for a HASS source is borne by the user at the end of useful life of that source. The Directive requires that the regulatory body should be satisfied with the financial provision for the end of life management of a HASS source before its use is authorised. It is likely that more than one kind of financial provision will be acceptable, including arrangements whereby the supplier takes on the responsibility for a disused source and this is reflected in the purchase or lease price. The actual costs of dealing with disused sources are not expected to change as a result of the HASS Directive.

In the historically unlikely case whereby a company goes into liquidation (insolvency) without leaving sufficient resources to dispose of its sources, the government is considering options for meeting those disposal costs.

- **Environmental costs**

The Regulations require the regulatory agencies to ensure that arrangements (including response plans and assignment of responsibilities) are in place for the recovery of all "orphan" sources.

The existing National Arrangements for Incidents involving Radioactivity (NAIR) scheme, which is co-ordinated by the Health Protection Agency (HPA) (formerly NRPB), ensures that appropriate expertise is available when radioactive materials are found in the public environment (but not on other premises). This is a voluntary scheme, with each participating organisation meeting its own costs. The HPA co-ordinates and provides training in the operation of the scheme, but the cost is small and is not separately identified in the HPA budget. However, the NAIR scheme does not cover source disposal or long-term storage. Any exceptional remediation or disposal costs will be met from central government funds.

- **Social costs**

No significant social costs were identified.

- **Regulatory costs**

The proposed legislation will complement the existing provisions for the control of radioactive sources required by the Basic Safety Standards Directive, as implemented under RSA93 and IRR99. Hence, the only substantial, additional regulatory effort

will be in issuing guidance, amending certificates of registration and setting up and maintaining a database of information on HASS sources, the latter derived from records provided and updated by the holders of such sources.

The initial cost of regulatory development is estimated as £300,000, including the establishment of a database and modifying the existing permit administration system (less than £100,000) and the preparation of guidance, training, etc. (£200,000). Ongoing additional duties are estimated to cost £1,000,000 per annum averaged over a 5 years period, to be recovered from the holders of HASS sources. Thus, the total regulatory costs arising from the proposed legislation will be about £1,060,000 per annum averaged over a period of 5 years.

- **Total costs**

The total costs, including compliance and regulatory costs, will be about £3.3 million per year (see summary table below and overall summary in Section 12).

Category of cost	Cost per annum
Economic	£2.2 million
Environmental	Small
Social	None identified
Regulatory	£1.06 million
Total	**£3.3 million**

6. Equity and Fairness

Those organisations benefiting from the use of HASS sources, include the suppliers of sources and the organisations using the sources in medicine, research, and industry. In many cases, it is members of the public who benefit from such practices and any additional costs will be absorbed in the cost of the services or products supplied. This survey has identified 6 suppliers of HASS sources within the UK, some of which arrange for the import of sources directly to the user and do not hold any sources within the UK. The number of HASS users is estimated to include the following principal organisations:
47 hospital radiotherapy departments;
12 universities;
100 industrial radiography companies;
5 industrial irradiation companies;
5 defence organisations (MOD and main contractors);
2 off-shore oil/gas service providers (main contractors);
4 other research organisations (main players);
4 other users (calibration and gauging).

In principle, the legislation will impact equally over all suppliers and users, assuming that the only substantial, additional requirements will be the provision of an annual return and notification of changes to the regulatory agency. Some options for meeting the requirement to arrange adequate financial provision for eventual source disposal

may result in part or all of the costs being shifted towards the time of purchase rather than the end of life of the source.

Those affected by the consequences of the loss of control of such sources would be members of the public exposed to radiation arising from a lost source accident and the metals recycling industry affected by the inadvertent smelting of a lost source. The UK metals recycling industry consists of an estimated 2,000 small scrap yards supplying 3 large companies, which supply processed metal scrap to the steel industry for smelting, some of which is imported from abroad.

On the basis of the principle that "the polluter pays", it is important that the compliance costs should be borne by the suppliers and users of the HASS sources. However, in the case of "orphan sources", the original owner of the source is unlikely to be known. In the case of the metals recycling industry, companies are encouraged to provide information and training on the actions to be taken on-site in the event of the discovery of an orphan source; these additional training costs are likely to be small.

Thus, the legislation will be fair in allocating liability to those benefiting from the use of high activity sealed sources (HASS), rather than those affected by the consequences of the loss of control of such sources.

7. Consultation with small business: the Small Firms' Impact Test

A number of small firms use HASS sources, such as the providers of site radiography services, and a number of small firms are involved in the recycling of scrap metals, where orphan sources may be discovered. The impact of the transposing legislation on small firms was assessed by consulting the appropriate industrial association for that sector, such as the British Institute of Non-Destructive Testing, the British Nuclear Industries Forum and the British Metals Recycling Association. The consultation survey identified small firms as being those with fewer than 50 employees and less than £4 million annual turnover.

The survey indicated that the impact of the legislation on small business is likely to be small in relation to annual turnover.

8. Competition Assessment

The following commercial markets are likely to be affected by the transposing legislation:

- manufacturers/suppliers of HASS sources, including importers of sources;
- users of HASS sources providing a commercial service, such as industrial irradiation and industrial radiography (including oil and gas industry);
- collection of waste HASS sources;
- metals recycling.

The market for manufacture/supply of sources currently consists of 6, mainly small, companies importing sources from abroad (EU, Canada, USA and former Soviet Union). Two of those companies only act as agents for the UK purchaser, do not hold

sources within the UK and are therefore not subject to the requirements of the Directive, thus giving them a small competitive advantage.

The principal markets for commercial services are thought to consist of 5 large companies providing irradiation services, about 100 mainly small companies providing radiography and analytical services, and 3 organisations providing calibration services.

The market for waste collection currently consists of 6, mainly small, companies accepting spent sources, either for disposal by another organisation or for exchange in the case of radiography sources.

The metals recycling industry consists of about 2,000 small scrap yards supplying 2-3 large companies, which supply processed metal scrap to the steel industry for smelting.

A simple assessment of competition impacts (competition filter test) in the above markets and the metals recycling industry suggests that the legislation is unlikely to have a significant detrimental effect on competition.

9. Enforcement and Sanctions

The provisions contained in the proposed legislation will be enforced using the existing enforcement regime contained in RSA93, IRR99 and NIA65, which include the serving of enforcement and prohibition notices in the event of non-compliance.

The legislation will be enforced by the appropriate Agency (Environment Agency in England and Wales, Scottish Environment Protection Agency in Scotland, Department of the Environment in Northern Ireland, Health and Safety Executive (for nuclear licensed sites in England, Wales and Scotland)).

Sanctions for non-compliance will be those existing under RSA93 or available under the HSWA74 (which are used in relation to IRR99).

10. Monitoring and Review

Monitoring and evaluating the effectiveness of the proposed regulatory arrangements would be performed as part of the existing inspection regime carried out by the regulatory agencies.

11. Consultation

During 2003 consultation took place with a representative number of organisations supplying or using HASS sources, together with relevant government organisations, to gather views on the likely costs and benefits arising from the Directive and to obtain data on the usage of such HASS sources. During 2005, the Department for Environment Food and Rural Affairs published the Consultation Document

"Implementing Council Directive 2003/122/Euratom on the Control of High Activity Sealed Sources and Orphan Sources" to seek views on the draft Regulations intended to implement the Directive. A summary of survey responses is included below.

i) Consultation within Government

The consultation documents were widely circulated to relevant government departments, devolved administrations, regulatory agencies and other statutory organisations.

ii) Public Consultation

Consultation took place with a representative number of organisations supplying or using HASS sources. The following groups of organisations responded to the surveys:

- manufacturers and suppliers of sources;
- users of sources in industry, medicine, research and teaching, and defence;
- radioactive waste disposal services;
- metals recycling industry.

In addition, the appropriate industrial or professional organisations were consulted.

iii) Summary of 2003 Survey Responses

HASS source users

The majority of HASS users consider that they would be not at all or slightly disadvantaged by the proposed legislation, as they already have existing measures in place, which would meet the requirements of the Directive to a greater or lesser extent.

However, industrial irradiation and radiography organisations considered that they would be very much disadvantaged by the additional administration. The estimates for additional costs of record keeping, training, etc. covered a wide range up to £100,000 per annum (in the case of industrial irradiation), but were generally less than £10,000 per annum. Those costs are likely to depend on the future arrangements for financing the disposal of unwanted sources and any increase in regulatory agency fees resulting from the requirements of the Directive. The benefits of the proposed legislation were not thought to be significant to the organisation, apart from improved efficiency, a greater public confidence in the use of radioactive sources and acting as a driver to reduce the activity of sources and to consider the use of non-radioactive alternatives.

This sector considered that implementation should be by amendment to existing legislation and of the certificate of registration, together with the issue of statutory guidance. There is a need to consider the situation of nuclear licensed sites, which are not subject to the registration requirement under RSA93, but would nonetheless be subject to the provisions of the Directive. Although enforcement by self-assessment was widely favoured, it was pointed out that this approach had proved to be inadequate and that increased surveillance was in fact required. Otherwise, enforcement under existing arrangements was favoured.

HASS source suppliers

Suppliers of HASS sources differed widely in their estimates of how much they would be disadvantaged by the proposed legislation. The estimates for additional costs ranged up to £35,000 per annum. It was commented that suppliers outside the EU would have a competitive advantage (leading to possible reduced sales for UK companies), unless the requirements of the Directive applied to all suppliers. The Directive does not apply to suppliers who do not hold sources in the UK, as arrangements for import are made directly with the user. The benefits of the proposed legislation were not thought to be significant, apart from improved efficiency and the general benefit to industry arising from the prompt disposal of unwanted sources.

Suppliers considered that implementation should be by amendment to existing legislation. Resources for enforcement needed to be focussed on areas of highest risk, such as bankruptcy and unwanted sources.

Waste HASS source collectors

Organisations involved in the collection of waste sources considered that they would be slightly disadvantaged, but the impact would depend on the legal liability for the return of sources. Additional costs were estimated to amount to as much as £100,000 per annum. The benefits of the proposed legislation were not considered to be significant. It was considered that enforcement of the legislation should be by self-assessment.

Metals recycling industry

The metals recycling industry considered that the proposed legislation would reduce the risk of radiation exposure and contamination from melting, shredding, processing, handling or otherwise dispersing undetected radioactivity in scrap metal. Companies would be slightly or not at all disadvantaged by the proposed legislation, which would have the benefit of helping to reduce the industry losses, approaching £1 million per annum, caused by other sources of low-level radioactivity in scrap metal. Additional costs of training would amount to less than £500 per annum for each site.

The metals recycling industry considered that implementation should be by amendment to existing legislation. Enforcement should be according to existing arrangements, as self-assessment has proved to be inadequate, requiring increased surveillance.

Arrangements for dealing with orphan sources

The initial survey indicated that the great majority of HASS users and suppliers considered that an extension of the existing NAIR scheme or a nationally co-ordinated Response Plan would be an appropriate arrangement to recover and dispose of orphan sources. Where the original ownership of the source could not be determined, it was generally considered that direct government funding should be available to cover the costs of dealing with orphan sources. A “levy” on the sale of new sources might be

appropriate, but would take time for the fund to accrue self-sufficiency. Government funding, at least in the interim, would be necessary to deal with major incidents.

End of life provisions for new sources

The initial survey also indicated that the great majority of HASS users and suppliers consider that return of the source to the supplier for disposal or recycling would be the best provision at the end of useful life of the source. The ultimate disposal costs should be included in the initial purchase price or, alternatively, the source should be leased from the supplier. This arrangement would reduce the time that redundant sources were stored while arrangements are made for disposal, reducing the possibility of loss. However, there are problems of assuming that the supplier will still be in business at the end of life of the source, of predicting future disposal costs and of enforcing contracts with suppliers outside the EU. It was suggested that these problems be overcome by paying into an investment bond or insurance policy, possibly underwritten by the government.

iv) Summary of 2005 Survey Responses

The survey sought views on the adequacy and completeness of the proposed arrangements relating to the draft regulations, including the potential options for adequate financial provision.

Detailed responses to the survey, together with the Consultation Document, are available at the DEFRA website www.defra.gov.uk/corporate/consult/hass-directive .

12. Summary and Recommendation

The information received in response to the consultation has provided broad estimates of the benefits and costs relating to the introduction of the proposed legislation and these are summarised in the table below in the form of rounded cost estimates.

Option	Total cost per annum (economic, environmental & social)	Total benefit per annum (economic, environmental & social)
Implementation of transposing legislation	£3.3 million	£2.2 million

The assessment indicates that the benefits to be gained in terms of health and economic costs averted will be outweighed by the costs arising from the transposing legislation. This conclusion regarding the balance of costs and benefits may be a consequence of the more rigorous regulatory regime, which has applied in the UK for a number of years.

It should be noted that the underlying data and assumptions used to estimate both the benefits and costs are subject to considerable uncertainty and that some of the benefits

are non-monetary and cannot be valued. Hence, the overall conclusion regarding the balance of benefits and costs will always be subject to considerable uncertainty.

13. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed: ***Elliot Morley***

Date: ***24th September 2005***

Elliot Morley

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ANNEX A. REPORTED INCIDENTS INVOLVING LOST RADIOACTIVE SOURCES

A1. GENERAL

A large number of incidents involving the loss of control of sealed radioactive sources have been reported over the last 50 years. A number of these incidents have resulted in excessive radiation exposure of members of the public, leading to death or serious injury. In other cases, lost sources have found their way into metal scrap destined for recycling, resulting in widespread environmental contamination requiring costly remediation.

Below is a summary of reported incidents involving lost sources, both worldwide and within the UK. As the regulatory requirements for reporting are likely to be different in various countries, it is inevitable that many cases are going unreported and that the number of reports received probably represents only "the tip of the iceberg" [A1].

A2. INFORMATION WORLDWIDE

A2.1. Loss of control of radioactive sources

Breaches in the security of radioactive sources cause them to become lost, stolen or simply abandoned and enter the public domain in an uncontrolled manner. There are no data on the number of these events worldwide [A1]. However, in the United States alone, the Nuclear Regulatory Commission (NRC) annually receives about 375 reports of lost, stolen or abandoned radioactive sources [A1, A2, A5]. Since 1986, about 60% of lost and stolen sources have not been recovered [A5]. It is not known what proportion of those reports refers to the category of "high activity sealed sources".

A recent example (1998) was the theft of 19 brachytherapy sources containing Cs-137 from a North Carolina hospital. In spite of extensive searches, the sources have not been recovered [A2].

A study reviewing the different management practices for sources in the EU estimated that a maximum of 70 are lost from regulatory control per year throughout the EU [A6]. This would equate to about 5-10 in the UK lost per year (see Section A3.1 below). It is not stated what proportion of those sources would be regarded as "high activity sealed sources".

A2.2. Radiation accidents involving radioactive sources

The IAEA has compiled a list of major accidents, which have resulted in radiation exposure sufficient to cause death or serious injury, drawing upon those accidents reported in the open literature [A1, A5]. The database contains a total of 136 accidents during the period 1945 to 1999, the majority of which (89 cases) involved radioactive sources. Averaged over the last 20 years, such cases have occurred worldwide at a rate of about 2 per year. The source materials were mainly Ir-192, Co-60 and Cs-137 in the form of radiography and medical sources (i.e. mainly "high activity sealed sources").

Reports of radiological accidents involving “high activity sealed sources” include the following.

- In 1985, an accident in Goiania, Brazil involved an abandoned teletherapy unit containing 50 TBq of Cs-137, which was stolen and the source capsule ruptured. Four severely exposed persons died, many others were seriously injured and the consequent decontamination of buildings and land lasted six months, all of which had a major economic impact on the region [A1].
- In 1994, a radiation source was stolen from a radioactive waste repository in Estonia, resulting in one death and serious injury to 2 other persons [A1].
- In 1996, a worker in Iran came across an abandoned Ir-192 radiography source while dismantling lagging and put the source into his overall pocket. The consequent over-exposure led to a severe injury [A1].
- In 1999, some abandoned Co-60 teletherapy sources in Turkey were dismantled, resulting in 10 persons receiving severe radiation injuries [A1].
- In 1999, a construction worker in Peru inadvertently picked up an uncontrolled Ir-192 radiography source, which he put into his pocket, resulting in severe radiation burns [A1].
- In 1997, a group of border guards in the Republic of Georgia were severely exposed to radiation from several sources containing Cs-137 or Co-60, abandoned in a former military barracks [A1].
- In 1979, an unshielded Ir-192 radiography source was accidentally left at a site in California and was picked up by a worker, resulting in severe radiation injury [A2].

Fortunately, no similar accidents causing deaths have occurred in the European Union, however their possibility cannot be completely ruled out [A6].

A2.3. Smelting incidents involving radioactive sources

Radioactive sources have found their way into metal scrap destined for recycling and, in a number of cases worldwide, smelting of the scrap has resulted in large quantities of contaminated steel and other metal product, some of which may have been exported to other countries.

More than 2,300 reports of sources found in scrap metal are contained in the US NRC database [A1, A2, A4]. During the period 1983 to 1998, a total of 59 cases worldwide (29 in the USA) were reported of radioactive material being smelted with scrap metal. The radioactive source materials were mainly Ir-192, Cs-137, Co-60, Ra-226 and Am-241. The source activity involved was not known in a large proportion of the cases, but, where reported, was generally greater than several GBq (corresponding to the definition of a “high activity sealed source”).

Twelve cases of melting of radioactive sources in scrap metal have been reported within the EU since 1990 [A1]. A recent incident of this type occurred at Algeciras in Spain in 1998, where a Cs-137 source was accidentally smelted, resulting in contaminated dust being detected over parts of France and northern Italy. Although the radiological health consequences were minimal, the economic consequences of the incident were large (see below).

While radiation exposure of workers and members of the public have, thus far, been low and generally below regulatory limits, the financial consequences have been large because of the costs resulting from decontamination, waste disposal and lost revenue during temporary shutdown of the plant [A2]. In the USA, steel mills have incurred costs averaging $8-10 million (£5-7 million) as a result of those events and, in one case, the cost was $23 million (£15 million). An incident at a large integrated steel mill could result in costs of $100 million (£67 million). In 1998, a Spanish steel mill accidentally melted a multi-GBq Cs-137 source, resulting in an estimated loss of €26 million (£17 million) [A5, A6].

Contamination of metal products resulting from the smelting of a radioactive source may lead to compensation claims by members of the public. For instance, in 1983, a number of buildings in Taiwan were found to have been constructed of steel contaminated with Co-60 [A3]. A group of residents filed an action against the Atomic Energy council for compensation of $3.4 million (£2.3 million).

The installation of facilities to detect radioactive sources in metal scrap has been successful in identifying over 400 devices in US scrap metal since 1983, with over half of the discoveries occurring in the last 5 years [A2, A5]. However, although the number of detected incidents in the USA and Canada has increased annually, the number of smelting events has remained at about 2 events per year [A4].

A3. INFORMATION IN THE UK

A3.1. Loss of control of radioactive sources

The Ionising Radiations Incident Database (IRID), which is operated by HPA on behalf of the UK regulatory agencies, covers radiological accidents and incidents involving actual or potential occupational and public radiation exposure [A7]. Although the database and reporting mechanisms came into existence in 1996, some "historical data" are also included. However, it is recognised that such incidents have been subject to considerable under-reporting, with the level of reporting varying between different industry sectors.

A total of 21 sealed sources of various types have been reported as lost since 1974 (the majority since 1990)[A8]. Within that total, 5 incidents involved the loss of "high activity sealed sources", all of which were subsequently recovered. The incidents concerned three Ir-192 radiography sources and two Cs-137 density gauges.

A3.2. Radiation accidents involving radioactive sources

Within the UK, there have been no recorded accidents involving lost sources since the introduction of the Radioactive Substances Act in 1960.

A3.3. Smelting incidents involving radioactive sources

The IRID database contains the case histories of 8 incidents since about 1990 in which radioactive material was detected, either in the scrap metal prior to smelting or in the smelted product [A8]. Only 2 of those cases may have involved "high activity sealed sources". In one case, a smelting company discovered significant radioactivity

in a consignment of processed material received from a foreign steelworks. It is probable that the radioactive material was Cs-137, which originated in the UK from an industrial weight gauge contained in scrap steelwork. The contaminated material was segregated and disposed of appropriately before the plant itself could become significantly contaminated. However, the remediation costs amounted to more than £1 million. In the second incident, radioactivity was discovered after processing a consignment of scrap imported from eastern Europe. Substantial quantities of process by-products were found to be contaminated with Cs-137 and Cs-134, requiring appropriate disposal.

A further incident occurred in 2000, at which a Pu-238 source was accidentally smelted at a Sheffield steelworks [A9]. The incident resulted in a considerable amount of contaminated slag, containing a total of about 150 GBq of Pu-238. The total cost of decontamination, radioactive waste disposal and lost production is not yet known, but is likely to run into millions of pounds.

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ANNEX B. ASSESSMENT OF CONSEQUENCES OF LOST SOURCES

B1. GENERAL

The objective of the assessment is to identify the events leading to the loss of control of sealed sources, to estimate the frequencies of those events and to quantify the likely health and economic consequences.

B2. POTENTIAL FOR LOSS OF CONTROL

There are a number of ways in which a sealed source may become lost, either permanently lost or reappearing in some way to present a potential hazard to man. The most likely loss scenarios are the following, based on historical evidence.

- A sealed source used for process measurement may become detached from the original equipment or lose its identification label (possibly in a fire). The lost source may be then picked up by an unsuspecting person, disposed with rubbish to a landfill site or disposed as metal scrap.
- In the case of redundant industrial plant, the sealed source may remain in place after shutdown of the plant and subsequently become incorporated in scrap destined for recycling.
- Theft of the source or the equipment that contains the source, with the intention of selling it as scrap.
- Bankruptcy of the source user, which would reduce or even suspend any control of the source.
- Intentional discarding of the source in order to reduce the liability of the owner with respect to long-term storage and disposal.
- Unintentional loss of the source due to lack of awareness of the user or poor record keeping.

The information required to assess the probability of each of the above loss scenarios is not readily available and it is therefore necessary to adopt a simplified approach based on conservative estimates of the parameters involved, derived from historical evidence.

The total number of HASS sources reported as lost in the UK is about 0.2 per annum, ie. one every 5 years [Annex A]. Recognising that this represents a situation of under-reporting, it may be assumed that a total of 0.5 per annum are lost, with about 0.3 per annum not recovered (a fraction 60% based on US experience).

The consultation survey indicated that approximately 4,300 HASS sources are in use within the UK, the majority of which are used for industrial radiography. Thus, the total number assumed lost per annum corresponds to less than 0.01% of the total number of HASS sources in use.

B3. POTENTIAL FOR CONTAMINATION AND RADIATION EXPOSURE

A proportion of the sealed sources, which have been lost and not subsequently recovered, will be later intercepted by workers or members of the public, leading to inadvertent radiation exposure. The likely exposure scenarios are the following:

- handling of the source after finding on a refuse tip (for example) or after theft (external exposure scenario);
- accidental or intentional damage of the source (after finding), leading to personal contamination (internal exposure and skin contamination scenario);
- smelting (or other processing) of scrap metal containing the source, leading to widespread contamination and inhalation of material dispersed in the atmosphere (smelting scenario).

The health and economic consequences of those scenarios are discussed below in more detail

B3.1. Handling of source

Handling of a "high activity sealed source" (greater than a few GBq) is likely to result in excessive radiation exposure of the skin and of the whole body, leading to serious clinical effects and possibly death [B1, B2]. Such "deterministic" health effects occur above a specific clinical threshold of radiation dose.

To the extent that any proposed legislation may result in saving several lives (or serious injuries), an indicative (median) value of life of approximately £1.6 million per life would be appropriate for a cost-benefit comparison involving public radiation exposure [B3]. Additional economic costs arising from such an incident would include disposal of the source, technical advice and regulatory effort.

B3.2. Damaged source

In the extreme situation that radioactive material from a damaged source is deposited on the skin (as happened in the Goiania accident in 1987), excessive radiation exposure of the skin would occur, leading to serious injury. Internal exposure due to inhalation or ingestion of radioactive material from a damaged source would lead to a whole body dose sufficient to cause serious injury and possibly death [B1].

B3.3. Smelting of source

The inadvertent smelting of a source would lead to the product (or by-products) being contaminated by radioactive material, release of radioactivity into the atmosphere and contamination of the plant. It is unlikely that plant workers or members of the public living in the vicinity would receive significant radiation exposure, although evacuation of plant staff and temporary relocation of the public might be necessary [B4].

The potential economic consequences of such an incident would include the following costs:

- loss of revenue during shutdown of the plant;
- decontamination of the plant;
- disposal of radioactive waste;
- emergency services;
- technical services (specialist advice, monitoring and sample analysis);
- medical treatment of contaminated persons;
- relocation of members of the public;

- legal costs and compensation;
- regulatory effort;
- social impact (public concern).

The overall impact of radioactivity found in scrap metal within the UK is discussed in recent reviews carried out by the metals recycling industry [B5, B6]. Although the above detailed costs have not been assessed, historical evidence suggests that a total average cost of about $10 million (£7 million) would be appropriate for such an event involving the smelting of a HASS source [Annex A].

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