1. This explanatory memorandum has been prepared by the Department Of Trade and Industry and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 The Order controls the export of certain high-activity radioactive sources.

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

3.1 None

4. Legislative Background

4.1 This Order is made in exercise of the powers conferred by sections 1, 5 and 7 of the Export Control Act 2002(1). In accordance with paragraph 2(1) of the Schedule to that Act, export controls may be imposed under that Act in relation to any goods the exportation or use of which is capable of having a relevant consequence.

4.2 The Secretary of State for Trade and Industry has determined that an activity involving the radioactive sources controlled by the Regulation is capable of having a relevant consequence, namely of leading to the carrying out anywhere in the world of (or acts which facilitate) acts of terrorism or serious crime anywhere in the world.

5. Extent

5.1 This instrument applies to all of the United Kingdom.


6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Order establishes a list of high activity radioactive sources which may not be exported without a licence. The introduction of the Order is motivated by a concern that certain criminal or terrorist groups may seek radioactive material ultimately for the purposes of terrorist activities. The controlled radioactive sources are defined as potentially carrying such a risk of use under the International Atomic Energy Agency’s...

7.2 The Order will help to minimise the risk that these higher activity radioactive sources might be diverted from their legitimate uses.

7.3 The radioactive sources concerned are used in a wide range of medical, industrial, agricultural and research applications. The vast majority of exports are to secure destinations for legitimate uses. The Order aims to support an effective control regime which minimizes the administrative burden on exporters. We will use flexible licence types wherever possible and base our licensing decisions on the following assessment criteria:

- the risk of the sources being diverted to terrorist use. In assessing this we shall rely on any relevant secret and open source intelligence, the track record of the end-user and the capability and attitude of the importing State as regards the security of these sources;

- our assessment of the commitment demonstrated by the recipient country in implementing and adhering to the IAEA Code of Conduct on the Safety and Security of Radioactive Sources; and

- whether the importing State has provided an import consent, where appropriate, for Category 1 type of radioactive source exports.

8. Impact

8.1 A Regulatory Impact Assessment has been prepared which concludes that the Regulation is likely to have minimal impact on the costs to business complying with the Regulation.

9. Contact

Nick Mitchell at the Department of Trade and Industry, Export Control Organisation, can answer any queries. Tel: 020 7215 8340 or email: nick.Mitchell@dti.gsi.gov.uk

DEPARTMENT OF TRADE AND INDUSTRY
July 2006
REGULATORY IMPACT ASSESSMENT FOR THE EXPORT OF
RADIOACTIVE SOURCES (CONTROL) ORDER 2006

Introduction

1 This is the Regulatory Impact Assessment (RIA) for the introduction of an Order
under the Export Control Act 2002 to control the export of certain radioactive
sources ("radioactive sources") as defined under Category 1 and Category 2 of
the IAEA Code of Conduct on the Safety and Security of Radioactive Sources
(IAEA/CODEOC/2004) which are not already controlled by existing export
legislation. A draft RIA was published 10 February 2006 as an annex to DTI’s
consultation document.

2 The draft considered three options by which we could comply with our
international commitments to control certain high activity radioactive sources.
They were (a) do nothing and wait for the European Commission to introduce
Community wide regulations; (b) Develop a voluntary regime; or (c) introduce
secondary legislation under the Export Control Act 2002 to control such exports.
The draft RIA concluded that the introduction of secondary legislation was the
best option and that by using a mix of different licence types the administrative
burden could be kept to a minimum whilst providing industry with regulatory
certainty.

Purpose and intended effect of measure

(i) The objective

3 The aim of the Order is to help minimise the risk of certain highly active
radioactive sources being diverted for criminal or terrorist purposes. The Order
helps to protect and enhance the reputation of British exporters abroad by being
seen to comply with international guidelines on the safe and secure exports of
such material.

(ii) The background

4 The IAEA Code of Conduct on the Safety and Security of Radioactive Sources
was agreed in 2003. Although not legally binding, the UK made a commitment to
implement it, including establishing an import/export regime to regulate
international trade in Category 1 and Category 2 radioactive sealed sources.

5 The radioactive sources concerned are used in a wide range of medical,
industrial, agricultural and research applications. We believe the vast majority of
exports are to secure destinations for legitimate uses. Our intention is to develop
an effective risk-based control regime, which minimises the administrative burden
on exporters. We will therefore use different licence types according to the level
of risk of diversion associated with each export. We believe that the majority of
transactions can be covered by either Open General or Open Individual licences.
The Open General will allow the export of Category 2 radioactive sources to a
number of destinations without the need for individual licences. The award of
Open Individual licences will be discretionary but will permit specified exports to
agreed destinations again without the need for individual licences thereby
allowing us to focus effort and resources on the most sensitive of destinations.

(iii) Rationale for government intervention
There is a risk that radioactive sources could be diverted and misused for terrorist purposes, specifically the assembly of radiological explosive devices. The introduction of export controls is intended to reduce this risk.

Consultation

(i) Within government

We have been working with other parts of Government including the UK environment agencies, the Department for Environment, Food and Rural Affairs, the Health and Safety Executive, Her Majesty’s Revenue and Customs, Foreign and Commonwealth, Home Office, Department of Transport and others in the development of this Order.

(ii) With industry

The exporters of these radioactive sources – many of whom are small businesses, are supportive of the aims of the IAEA Code of Conduct and have been very helpful in our research of their industry. They have indicated their willingness to comply with the new regulation. They recognise that our aim is not to hinder exports which are to well established and trusted end-users in destinations with robust controls, but to minimise the risk of these sources being diverted for ill-use.

The consultation received seven responses in total, 4 from industry and three from Government agencies. None referred directly to the RIA but three of the companies provided estimates on the costs of administering the new control. Two estimated that the additional cost of complying with the new rule would be about £10k a year i.e an additional quarter of a full time employee per company and the other thought it would be about £2k. Exporters felt however that the greater potential cost would be if there were significant delays in processing their licences. We accept this point and will endeavour to process licences as quickly as possible. The other company respondent provided a short note stating that the new controls would be an additional and unnecessary burden on an already well regulated industry.

The responses did not identify any issues that were not taken into account in the draft RIA.

Options

We considered three options:

- Option 1: Do nothing and wait for the European Commission to develop new Regulations which the UK can adopt;

- Option 2: Develop a voluntary regime whereby industry simply notifies DTI of exports.

- Option 3: Introduce our Order under the Export Control Act 2002 to control exports of the specified Category 1 and Category 2 radioactive sources.

Advantages of each are:
• Option 1: The European Commission has competence to develop Regulations in this area for the whole of the European Union. By leaving the Commission to develop the legislation ensures consistent regulations with the other Member States (but see also option 3 below). It also means that industry would not yet be required to comply with the legislation.

• Option 2: The advantage is that it could minimise the administrative burden on business and Government. It would also enable us to “pilot” the regime and use the experience to help inform development of any eventual EC regulations.

• Option 3: A separate order under the Export Control Act would provide industry and enforcement bodies with regulatory certainty as well as the business benefits listed in section 5 below. It is also likely that any future EC regulation will need to be transposed into UK legislation and that this would most likely be done for exports through the Export Control Act. By acting now we can significantly inform development of an EU-based regime as well as be ready to implement it. In reality, any eventual EU regime, because it will also be based on the IAEA Code, is likely to be very similar to a UK regime.

13 Risk associated with each option:

• Option 1: The EC is not expected to develop Regulations for a considerable period and during the interim we leave ourselves open to the threat of these radioactive sources being diverted and used for terrorist purposes. France and Germany too propose to develop interim arrangements because of the potential threat.

  UK exporters of this material are recognised as setting the highest standards in ensuring that sources are traded in line with national and international regulations. By waiting until the EC develops regulations we risk UK exporters appearing to be falling short of these international commitments and they potentially risk losing contracts to exporters from countries that have implemented the controls. In addition there would be an uneven international playing field prior to the introduction of any EU scheme: France and Germany already have plans in train to introduce domestic arrangements in the interim period.

• Option 2: A voluntary scheme is likely to cost industry and Government as much to administer as a statutory one but would not necessarily give industry regulatory certainty, or a level playing field nor would help to facilitate enforcement action against illegitimate traders.

• Option 3: A separate order under the Export Control Act would provide industry and enforcement bodies with regulatory certainty. It is also likely that any future transposition of EC regulations into UK legislation would most likely be done for exports through the Export Control Act. By acting now we minimise the disruption caused by a subsequent move to an EU-based regime. We also minimise the risk that UK exporters will be penalised by countries to which they wish to export because there is no UK regime in place. The advantage of this option is that is it
would be built around existing administrative procedures for export control and therefore minimise the administrative burdens on business.

Costs and Benefits of the preferred option

Option 3 (preferred option)

14 The implementation of the Order provides industry with a number of benefits through:

- Regulatory certainty – there has been concern that without statutory underpinning there is a risk of industry/regulators not fully understanding what is required of them;
- Reassuring the international community – some countries have previously indicated that they would be less willing to allow exports from destinations without controls in place.
- Enhancing the reputation of UK exporters – HMG actively controlling these goods helps to minimise the risk of diversion and enables British exporters to be seen as setting the standard for good practice; and
- Having flexible risk based open licensing allows resources to be focussed on the more sensitive export destinations.

15 There are also benefits for society and consumers at large. These include:

- Ensuring that exports are controlled and that the risk of diversion is minimised;
- Ensuring that legitimate trade is allowed with minimal bureaucracy; and
- Enhancing the reputation of UK firms abroad benefits the rest of the economy in the long run.

16 We do not believe that the new Order will introduce significant administrative costs on UK industry. Two of our three company respondents have confirmed that the actual cost to administer the requirements of the Order represent a small addition to their overall administrative burden ie approximately £10k a year which is the equivalent to a quarter of a full time employee. We believe that this is because:

(a) There is already a complex regulatory framework in place in the UK to safely manage the use, storage, transportation and disposal of radioactive sources to which industry has to conform. Compliance with our Order will require them to submit and retain only a subset of the information they already record for these other regulations;

(b) By using a mix of different licence types including Open licensing for exports to safe destinations and well established end-users, we will minimise the amount of paperwork and time industry has to spend in complying with this Order;

(c) We have aimed to keep any changes to a minimum.” We have therefore kept out of scope of the Order activities which do not add to the risk of diversion but which, if included, would create substantial administrative burdens on industry;

(d) We estimate that annually- even without the use of Open General Export Licences the number of export applications necessary for the whole UK industry will be relatively small – approximately 200 Standard Individual Export Licences and about 50 Open Individual Export Licences. This is based on the fact that
experienced exporters will be issued OIELs to export radioactive sources to well established and authorised importers in certain safe destinations thus minimising the need to obtain separate individual SIEL for each source.

**Business sectors affected**

17 Radioactive sources are extensively and commonly used in a wide range of medical, industrial, agricultural and research applications. They vary widely in physical size and properties, their radioactivity level and the ease of access. Our informal consultation with industry and an analysis of the radioactive sources market suggests that:

(a) There are a relatively small number of radioactive source manufacturers and suppliers based in the UK who will be affected by this new control. These companies are the primary exporters (and importers) of radioactive sources and the main distributors of sources once they are in the UK. They already have to comply with a wide range of UK and international regulations.

(b) With the exception of one or two (who are part of larger international healthcare companies), the great majority of the firms involved in the industry are SMEs.

(c) Sources are exported on their own or as part of other equipment. The Order does not seek to control the equipment only the source(s) contained within it. We estimate that the vast majority of exports are individual sealed radioactive sources as opposed to exports of equipment with the sources incorporated (a ratio of about 10:1).

(d) We believe that a significant proportion of exports (annual average of about 1500 sources) are to only a handful of countries. Most of which have well established and robust infrastructures to manage radioactive sources safely and securely. For example, our research suggests that around 50% of total exports of Categories 1 & 2 are to the US; about 15% to the EU and 15% to Japan – see tables 1 and 2 below.

(e) A significant proportion of the trade is also repeat business with well-established and trusted relationships between the supplier and customer.

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2 Less than a dozen firms
3 Using HMRC Tariff Code data for radioactive sources
Table 1: UK Exports by Country (Categories 1 and 2)

- 65% of exports go to USA and Japan
- A further 11% go to Germany, China, France, Switzerland and Australia
- The remaining 24% cover 124 other countries.

Table 2: UK Exports by Region (Categories 1 and 2)

- 53% of exports go to North America
- Another 23% go to Asia and Oceania (out of these, 65% go to Japan and 11% to China)
• 15% go to the European Union
• The remaining 9% are spread thinly among the other 5 regions

**Consultation with small business: the Small Firms’ Impact Test**

18 As indicated above the sector is relatively small with fewer than a dozen firms in the UK that actively export the controlled radioactive sources. Many of these are small businesses and over the course of 2005/06 have consulted them informally about the implementation of the IAEA Code. They have indicated their full support to comply with our regulation recognising that we will offer them Open licensing where possible to minimise their administration costs. These firms already have to deal with a variety of national and international laws and our understanding is that by utilising information already held for other purposes this new Order will not force them to have to hire additional staff or introduce new systems.

**Competition Assessment**

19 The Order will have no adverse effect on competition since the firms active in this market will be able to continue competing against each other. In addition the users of such sources in the UK will see no change as these controls are not intended to control imports.

**Enforcement and sanctions**

20 Offences will be enforced, as with strategic exports, by Her Majesty's Revenue and Customs. Offences for export in breach of a prohibition are contained in the Customs and Excise Management Act 1979. The maximum penalty for the most serious offences of deliberately flouting controls on exports is set at 10 years, the maximum penalty permitted under the Export Control Act 2002.

**Monitoring and review**

21 We will monitor the impact of this Order on industry by conducting a survey after the first year of its operation.

**Summary and recommendation**

22 We believe that Option 3 – ie developing a new Order under the Export Control Act 2002 provides the best means of meeting our international commitments on non-proliferation and maintaining the good reputation of the UK radioactive sources industry. The Order provides regulatory certainty to industry, enforcement bodies and foreign Authorities, which together will minimise the risk of diversion to undesirable end users/uses. Importantly, the use of open and general licences will give UK industry appropriate flexibility in complying with the proposed Order.

**Declaration**
I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed Malcolm Wicks
Malcolm Wicks, Minister of State for Energy
Date 7th July 2006

Contact

Nick Mitchell
Head, Special Casework Licensing Unit
Export Control Organisation
Department of Trade and Industry
Kingsgate House
66-74 Victoria Street
London
SW1E 6SW

Tel: +44 (0) 20 7215 8340
Fax: +44 (0) 20 7215 4539
Email: Nick.Mitchell@dti.gsi.gov.uk