SAND REPORT SAND2003-3767

Unlimited Release Printed October 2003

## The Adequacy of Current Import and Export Controls on Sealed Radioactive Sources

John R. Cochran, Susan W. Longley, Laura L. Price and Kendra J. Lipinski

Prepared by Sandia National Laboratories Albuquerque, New Mexico 87185 and Livermore, California 94550

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#### The Adequacy of Current Import and Export Controls on Sealed Radioactive Sources

John R. Cochran Dangerous Materials Mitigation and Disposition Department

> Susan W. Longley Advanced Nuclear Concepts Department

Sandia National Laboratories P.O. Box 5800 Albuquerque, New Mexico 87185

> Laura L. Price Beta Corporation 7212 W. Aurora Drive Glendale, AZ 8530

Kendra J. Lipinski (summer student) Advanced Nuclear Concepts Department

#### Abstract

Millions of sealed radioactive sources (SRSs) are being used for a wide variety of beneficial purposes throughout the world. Security experts are now concerned that these beneficial SRSs could be used in a radiological dispersion device to terrorize and disrupt society. The greatest safety and security threat is from those highly radioactive Category 1 and 2 SRSs. Without adequate controls, it may be relatively easy to legally purchase a Category 1 or 2 SRS on the international market under false pretenses. Additionally, during transfer, SRSs are particularly susceptible to theft since the sources are in a shielded and mobile configuration, transportation routes are predictable, and shipments may not be adequately guarded.

To determine if government controls on SRS are adequate, this study was commissioned to review the current SRS import and export controls of six countries. Canada, the Russian Federation, and South Africa were selected as the exporting countries, and Egypt, the Philippines, and the United States were selected as importing countries. A detailed review of the controls in each country is presented.

The authors found that Canada and Russia are major exporters, and are exporting highly radioactive SRSs without first determining if the recipient is authorized by the receiving country to own and use the SRSs. Available evidence was used to estimate that on average there are tens to possibly hundreds of intercountry transfers of highly radioactive SRSs each day. Based on these and other findings, this reports recommends stronger controls on the export and import of highly radioactive SRSs.

## Acknowledgments

This work was funded by the U.S. Department of State, Office of the Senior Coordinator for Nuclear Safety. Within that office, Kirsten Cutler, Ron Burrows, Jeff Miller, and Warren Stern facilitated contacts and assistance from the U.S. Nuclear Regulatory Commission, the International Atomic Energy Agency (IAEA) and the Russian Federation. Andrew Sowder of the Office of the Senior Coordinator provided very significant support, which improved the clarity and content of this report.

Ahmed Hasan and Sandia National Laboratories' Integrated Management Program for Radioactive Sealed Sources in Egypt in Department 6804 supported this study and provided information and contacts related to Egyptian import regulations. Len Connell and staff in Sandia's Department 9745 prepared Appendix A at a very reasonable cost using recently acquired classified information. Paul Rexroth in Sandia's Department 5326 also provided significant efforts to try to locate information on Russian Federation regulations.

Within the IAEA, Brian Dodd, John Wheatley, and Vladimir Averkiev provided their support in attempting to locate information on Russian Federation regulations. Victor Levin and Stan Vatnitsky supplied insight into the number and types of brachytherapy SRSs used worldwide.

Mike Smith at the South African Nuclear Energy Corporation provided a valuable service in sharing information on the South Africa's regulatory structure. Brenda Beriault and Bob Irwin of the Canadian Nuclear Safety Commission helped the authors understand the Canadian regulations. U.S. Nuclear Regulatory Commission representatives Karen Henderson, John Hickey, Marvin Peterson, and Kirstin Riesbeck supported and reviewed the section on U.S. import regulations.

## Contents

1. Introd	uction		19
2. Scope			21
2.1	Sco	ope of Work	21
2.2	Ov	erview of this Study	22
3. Backgi	round		23
3.1	Use	e of Sealed Radioactive Sources	23
	3.1.1	Medical Applications	23
	3.1.2	Research and Education Applications	24
	3.1.3	Industrial Applications	24
3.2	Nu	mber and Categorization of Sealed Radioactive Sources	26
3.3	Pro	oduction and Distribution of Sealed Radioactive Sources	27
3.4	Pro	operties of Most Commonly Used Radionuclides	27
3.5	Ma	ignitude of Worldwide Trade in Radioactive Sources	
	3.5.1	Magnitude of Worldwide Shipments of Radioactive Materials	28
	3.5.2	Magnitude of Worldwide Trade in Radioactive Sources	
3.6	Ac	cidents Involving Sealed Radioactive Sources	
3.7	Sel	lection of Exporting and Importing Countries	
4. Export	ting Cou	Intries	
4.1	Ca	nada	
	4.1.1	Introduction/Nature of Exports	35
	4.1.2	Regulatory Requirements	
	4.1.3	How Laws Address Specific Questions	42
	4.1.4	Summary Table	44
4.2	The	e Russian Federation	44
	4.2.1	Introduction/Nature of Exports	44
	4.2.2	Regulatory Requirements	45
	4.2.3	How Laws Address Specific Questions	49
	4.2.4	Summary Table	50
4.3	Soι	uth Africa	51
	4.3.1	Introduction/Nature of Exports	51
	4.3.2	Regulatory Requirements	51
	4.3.3	How Laws Address Specific Questions	
	4.3.4	Summary Table	55
5. Import	ting Cou	ıntries	57
5.1	Ara	ab Republic of Egypt	57
	5.1.1	Introduction/Nature of Imports	57
	5.1.2	Regulatory Requirements	57
	5.1.3	How Laws Address Specific Questions	59
	5.1.4	Summary Table	59
5.2	Rej	public of the Philippines	59
	5.2.1	Introduction/Nature of Imports	59
	5.2.2	Regulatory Requirements	60

	5.2.3	How Laws Address Specific Questions	
	5.2.4	Summary Table	
5.3	Un	ited States of America	
	5.3.1	Introduction/Nature of Imports	
	5.3.2	Regulatory Requirements.	64
	5.3.3	How Laws Address Specific Questions	71
	5.3.4	Summary Table	73
6. Lapses	in Imp	ort / Export Control	75
6. Lapses 7. Summa	in Impo try and	ort / Export Control Recommendations	75 77
6. Lapses 7. Summa 7.1	in Impo try and Sur	ort / Export Control Recommendations mmary of Information Exporting Countries	
<b>6. Lapses</b> <b>7. Summa</b> 7.1 7.2	in Impo ary and Sur Sur	ort / Export Control Recommendations mmary of Information Exporting Countries mmary of Information Importing Countries	
6. Lapses 7. Summa 7.1 7.2 7.3	in Impo ary and Sur Sur Ke	ort / Export Control Recommendations mmary of Information Exporting Countries mmary of Information Importing Countries y Findings and Recommendations	

# Figures

Figure 4-1. Ge	neral Scheme of Russia	ian Federation Management of SRS Exports (after
Ala	rdin, J.M., et al. [1999]	

# Tables

Table 3-1. Estimate of Worldwide Trade in Category 1 and 2 SRSs	31
Table 4-1. Examples of Canadian exports produced by MDS <sup>™</sup> Nordion <sup>™</sup>	36
Table 4-2. Summary of Canadian Export Requirements	43
Table 4-3. Summary of Canadian Export Notification and Tracking Requirements	44
Table 4-4. Summary of Russian Regulations	50
Table 4-5. Summary of South African Notification and Tracking Requirements	56
Table 5-1. Summary of Egyptian Notification and Tracking Requirements <sup>1</sup>	59
Table 5-2. PNRI Regulations for Possessing Sealed Radioactive Sources	61
Table 5-3. Summary of Philippine Notification and Tracking Requirements	63
Table 5-4. NRC Regulations for Possessing SRSs	67
Table 5-5. Summary Table for U.S. NRC Notification and Tracking Requirements for	
Exempt, Generally Licensed, and Specifically Licensed SRSs	70
Table 5-6. Summary of U.S. Notification and Tracking Requirements	73
Table 8-1. Summary of Countries Regulations Governing Export of SRS	78
Table 8-2. Summary of Countries Regulations Governing Import of SRS	80

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## **Executive Summary**

Millions of sealed radioactive sources (SRSs) are in use worldwide. The radiation from these SRSs is used in agriculture, manufacturing, construction, research, consumer goods, space exploration, teaching, military applications, and medicine. For the treatment of cancer, radiation is an indispensable tool: about half of all patients are treated with radiation. In many cases, the SRSs are used as beneficial tools for tasks that would otherwise be difficult or impossible.

Security experts are now concerned that these beneficial SRSs could be used in a radiological dispersion device (RDD) or "dirty bomb" to terrorize and disrupt society. The concerns of security experts are illustrated by an accident in Goiânia, Brazil, where a 50 terabecquerel (1,300 Ci) Cesium-137 SRS was stolen and deliberately cut open. Four people died, several hundred suffered health effects, acute anxiety ensued, and 112,000 people sought medical attention. Additional social disruptions included discrimination against people and products from the region, a dramatic decline in tourism, and several years of negative impact on the local economy. Many buildings had to be destroyed; other buildings had to be decontaminated and soils removed, generating thousands of cubic meters of radioactive wastes and costing millions of dollars. Cleanup efforts took several years.

In addition to the analogue provided by the accident in Goiânia, security experts at Sandia National Laboratories (Sandia) and other national laboratories have also conducted classified simulations of the consequences of using a SRS in a RDD. These experts have determined that a major RDD event could cost tens of billions of dollars and initiate disruptions that could ripple through large segments of U.S. society. The results of the simulations are presented in Appendix A, which is a stand-alone, classified report.

According to the International Atomic Energy Agency (IAEA), the greatest safety and security threat is from those highly radioactive SRSs capable of causing death after a few minutes to a day of exposure to the unshielded radioactive material. The IAEA classifies these sources as Category 1 and 2 SRSs.

U.S. and international experts have identified as a top priority the need to locate, recover, and secure orphan sources to prevent their use in a RDD. Orphan sources are those sources that are not under regulatory control either because the source has never been under regulatory control, or because it has been improperly transferred, abandoned, lost, or stolen.

In addition to acquiring orphan SRSs, rogue countries and terrorists may seek to purchase the materials needed for constructing weapons of mass destruction. Without adequate controls, it may be relatively easy to legally purchase a Category 1 or 2 SRS on the international market under false pretenses. Additionally, during transfer, SRSs are particularly susceptible to theft, since the sources are in a shielded and mobile configuration, transportation routes are anticipatable, commercial carriers may be responsible for the shipping and the shipments may not be adequately guarded. Consequently, government controls on SRS exports and imports are crucial for preventing illicit SRS trafficking.

To determine if government controls on SRS exports and imports are currently adequate, this study was commissioned to review SRS properties, uses, and categorization, and to assess:

- The magnitude of the worldwide trade in SRSs,
- The adequacy of SRS export regulations of three countries,
- The adequacy of SRS import regulations of three countries, and
- Examples of past lapses in import or export control of SRSs.

#### **Properties**

Most SRSs occupy less than 15 cc (1 inch<sup>3</sup>), are airtight, durable, and appear harmless. SRSs may contain one of hundreds of radioisotopes with activities that range from less than 1 MBq (~ 27  $\mu$ Ci) to several PBq (~ 27 kCi). The majority of SRSs have activities less than four MBq (100 mCi). Depending on the encapsulated material(s), SRSs may emit neutrons and/or alpha, beta, or gamma radiation. The half-lives of the typical radioisotopes range from 74 days for Irriduim-192 (Ir-192) to 1,600 years for Radium-226 (Ra-226).

#### Uses

Hospitals and medical clinics are among the largest users of SRSs. The radiation to treat cancer may be provided by SRSs in teletherapy machines, multibeam teletherapy machines, and by brachytherapy. Other applications include the use of Ir-192 in industrial radiography and the use of large neutron and gamma sources in oil, gas, and water "well logging." The most common industrial SRSs are in level and thickness gauges. Radioisotope thermoelectric generators (RTGs) use heat generated by decay of radioactive isotopes to produce electrical power. RTGs have no moving parts and can operate for over a decade without refueling. Industrial irradiators, containing Cobalt-60 or Cesium-137 (Co-60 or Cs-137), are used to sterilize medical products, as well as meat, fresh vegetables, and other foods. SRSs are also used for educational and research purposes. It is believed that all 136 Member States (countries) of the IAEA use SRSs daily, but only eight of these produce the majority of radionuclides distributed worldwide through a complex manufacturing and distribution network.

*Unwanted SRSs:* Approximately 20% of all SRSs are spent or disused and unwanted. Unwanted Ra-226 SRSs are a particular problem because of the long half-life and water-soluble form of the radium. Charity efforts in the 1950s and 1960s inadvertently placed Ra-226 SRSs in developing countries least able to mange very long-lived radioactive wastes. For these countries, one solution is to transfer the disused SRSs to a developed country with the infrastructure and experienced personnel to properly manage these long-lived radioactive wastes. This study evaluates whether or not the three exporting countries examined will allow reentry of disused SRSs.

*Accidents:* Accidents with significant health consequences have occurred with regularity around the globe; in any given year, there are approximately one to three serious accidents. Some of these accidents, such as the Goiânia, Brazil incident, have caused widespread social disruptions, denied access to large areas of cities, contaminated land and buildings, and exposed the public to high, even fatal, doses of radiation.

#### Categorization

The IAEA has classified SRSs into five categories with respect to possible health effects. This categorization allows the IAEA and its Member States to apply a graded approach to the management of SRSs. Category 1 and 2 sources are of greatest concern from safety and security

perspectives. Typical radionuclides in Category 1 and 2 SRSs include Co-60, Cs-137, and Ir-192, and common applications include RTGs, irradiators, teletherapy, fixed multibeam teletherapy (gamma knife), industrial gamma radiography, and high/medium dose-rate brachytherapy.

#### Magnitude of Worldwide Trade

There is no existing estimate of the annual number of intercountry transfers of civilian Category 1 and 2 SRSs. This report used published summary statistics, a number of assumptions, and best professional judgment to estimate the number of Category 1 and 2 SRSs shipped between countries annually. On average, there are tens to hundreds of intercountry transfers of Category 1 and 2 SRSs each day. With such a large number of transboundary shipments, there is significant opportunity for unauthorized access through diversion, theft, or acquisition under false pretenses.

#### Controls in Exporting Countries

The criteria for selecting the three exporting countries and the three importing countries for a detailed review included the desire to sample a cross-section of developed and developing nations and the desire to sample a cross-section of continents. Canada, Russia, and South Africa were selected as the exporting countries, and Egypt, the Philippines, and the U.S. were selected as importing countries.

Canada: Canada is reported to produce 85% of the world's Co-60 and over one-half of the world's medical sterilizers and Co-60 therapy machines. They have a significant legal infrastructure that addresses such issues as customs, dual use, taxation, United Nations embargos, safety, and nuclear non-proliferation. Canada "verifies" before exporting items to countries on the Area Control List or before exporting items on the Export Control List (ECL). An export permit must be obtained for the export of any goods on the ECL. SRSs containing radionuclides that may be fissile (e.g., Plutonium-239) or fertile are on the ECL, and Canada verifies before exporting SRSs that contain fertile or fissile radionuclides. However, most SRSs containing fissile/fertile radionuclides are not Category 1 or 2 SRSs<sup>1</sup>. For the purposes of this report, verification means the materials are not exported until Canada has confirmed that the material is shipped to organizations that have provided proof that they are authorized by their regulatory authorities to possess such material. Non-fissile radioactive materials (such as Co-60) in SRSs are not on the ECL and Canada does not, as a country, verify before exporting nonfissile Category 1 and 2 SRSs. MDS<sup>™</sup> Nordion,<sup>™</sup> the major Canadian SRS exporter, does verify the validity of the recipient; however, this is done as a good business practice and not because verification is required by Canadian law.

*Russian Federation*: Russia's SRS regulations are not readily available in English or on the worldwide web, and the effort necessary to acquire information about Russian export regulations was roughly equal to the effort necessary to get information on the other five countries combined. The production and circulation of Russian SRSs is formidable. Currently, about 90% of all new SRSs produced in Russia are exported. Since 1990, Russian nuclear exports have increase 280%. A number of Russian and international firms distribute SRSs produced in Russia are involved in the regulation and export of nuclear

<sup>&</sup>lt;sup>1</sup> Section 3.2 contains an important note on the IAEA Categorization system and alpha-emitting radionuclides.

materials. The Federal Nuclear and Radiation Safety Authority of Russia, GOSATOMNADZOR (GAN), is the highest nuclear regulatory body in the Russian Federation. GAN licenses all nuclear activities. The State Committee of Sanitary-Epidemic Control, GOSSANEPIDADZOR, a subdivision of The Ministry of Health, is responsible for issuing limited certificates for the right to deliver, distribute, and use ionizing radiation sources. The Russian Federation's Ministry for Atomic Energy, MINATOM, is responsible for producing SRSs and other related activities.

The Ministry of Commerce is responsible for regulating import and export within the Russian Federation. A permit must be obtained from the Ministry of Commerce in order to export any item on the goods list of foreign economic activities, and all radioisotopes are on this list. All fissile/fertile radionuclides are controlled with exporting procedures in line with the nuclear non-proliferation procedures determined by the IAEA; thus, Russia applies special controls to exporting SRSs that contain fissile materials. For non-fissile radionuclides, it does not appear that verification is required as a condition for exporting Category 1 and 2 SRSs from Russia.

*South Africa:* The South African regulatory system is refreshingly simple. The National Nuclear Regulator of South Africa is responsible for regulating nuclear installations. However, the export of sources from the South African Nuclear Energy Corporation (NECSA) facilities is regulated by the Department of Health. To export SRSs from South Africa, the Department of Health issues NECSA an "authority," which is similar to a license. To assure that sources are exported to countries with the infrastructure to safely and securely manage the material, exports are only made to countries that are IAEA Members and comply with IAEA and other transport regulations. Additionally, the authority requires that "Radioactive material or contaminated equipment shall only be shipped to organizations outside South Africa which have provided proof that they are authorized by their regulatory authorities to possess such material or equipment."

In summary, Canada and Russia are major SRS exporters that export Category 1 and 2 SRSs without first determining if the recipient is authorized by the receiving country to own and use the SRSs. Canada and Russia "verify" before exporting SRSs that contains fissile or fertile materials, even though SRSs containing fissile or fertile radionuclides are rarely Category 1 or 2 SRSs. The export of fissile/fertile materials has long been recognized as a security (nuclear non-proliferation) hazard, and such exports are controlled. The authors speculate that Category 1 and 2 SRSs have not been recognized as a security hazard and there are fewer controls on the export of Category 1 and 2 SRSs. Even in the absence of specific laws and regulations, the authors believe that it is in the best interests of suppliers to verify the legitimacy of recipients before shipping.

#### Controls in Importing Countries

The three importing countries of Egypt, the Philippines, and the U.S. represent a broad crosssection of continents and economies.

*Egypt*: Approximately 200 SRSs were imported to Egypt in 2002. The Executive Office for Radiation Protection (EORP), Ministry of Health and Population issues licenses for possession and use of SRSs. Egyptian law does not differentiate between SRSs containing fissile and non-fissile radionuclides. A license for possession carries with it the authorization to import SRSs;

however, a permit to import must be obtained from EORP. EORP keeps a registry of all SRSs in Egypt, as well as records of SRSs imported and exported.

*Philippines*: The Philippine Nuclear Research Institute (PNRI) reports that, in 2001, it issued 437 certificates for the import of SRSs. A permit must be obtained from the PNRI before the materials can be imported. The PNRI grants the right to import radioactive materials to anyone with a license to own radioactive materials. The PNRI has a registry of the SRSs in the Philippines.

*United States:* The U.S. regulatory system governing SRSs is complex. As a simplification, the regulation of SRSs containing naturally occurring radioactive materials is delegated to each of the 50 states. Regulation of SRSs used in "atomic energy defense activities" is delegated to the U.S. Department of Energy. The U.S. Nuclear Regulatory Commission (NRC) regulates the remaining SRSs. The NRC exempts from regulation those items owned by the U.S. Department of Defense that contain "special nuclear materials." As allowed by U.S. law, the NRC has transferred its authority to regulate certain SRSs to 32 states, known as Agreement States, while the NRC has regulatory authority over SRSs in the remaining 18 states. Independent of all other factors, such a complex system hinders the comprehensive regulation and tracking of imported SRSs.

The exact number of SRSs imported annually to the U.S. is unknown, although believed to be substantial. The NRC regulates SRSs by granting either a specific or general license, and some SRS devices are exempt from licensing. A specific license is granted for the operation of SRS devices that require special safety measures; the license is only granted to a person who has met certain requirements and has filed an application with the NRC. General licenses are for SRS devices that require minimal radiation safety measures because the specific SRS devices are of robust designs. A general license is issued through NRC regulations, and the licensee does not file a specific application with the NRC. Inherently safe SRSs devices (e.g., smoke detectors) are issued to persons exempt from licensing. The NRC estimates that there are about 200,000 (general and specific) licensees in the U.S., and that these licensees have about 2,000,000 devices; each typically containing one to four radioactive sources. The NRC and its Agreement States license about 21,000 specific licensees nationwide. These numbers do not include SRSs containing naturally occurring materials or SRSs owned by the DOE.

A person is authorized to import the radioactive source under a general import license if (1) they are authorized to possess the source and (2) the source is byproduct, source, or special nuclear material in less than formula quantities. If the SRS contains formula quantities of strategic special nuclear material (i.e., fissile material), the source may still be imported under a general import license, but the NRC must be notified. Registration (but not prior permission to import) is required for sources exceeding certain activities (e.g., if the SRS exceeds 370 MBq (10 mCi) of Cs-137).

SRSs that require a specific license to possess include those used in industrial radiography, irradiators, well logging, and gauging devices. Specific licensees are not required to report imports to the NRC, but in most cases, licensees are required to report their inventory of SRSs on a regular basis.

In Egypt, the Philippines, and the U.S., a license to possess a type of SRS carries with it the right to import that type of SRS. Egypt and the Philippines also require government authorization to import. Category 1 and 2 SRSs can be imported to the U.S. without government permission – the license to possess includes authorization to import, without additional government approval. Special permission to import SRSs into the U.S. is only required for formula quantities of strategic special nuclear materials.

In the U.S., the import of fissile/fertile materials has long been recognized as a security and proliferation hazard, and such imports are controlled. The authors speculate that in the U.S., Category 1 and 2 SRSs have not been recognized as a security concern; consequently, few controls have been placed on the import of Category 1 and 2 sources.

#### Lapses in Import/Export Controls

No instances of lapses in import or export controls were identified. However, examples of illegal trafficking in SRSs and incidences related to import and export of SRS were encountered. The IAEA database on illegal trafficking lists 263 confirmed instances of illegal transfers since 1993. Approximately 45% of these cases involved SRSs containing Cs-137, Co-60, Americium-241 and Strontium-90. By definition, the examples of illegal trafficking are considered success stories, as laws were in place and the perpetrators were apprehended.

An example of an instance indirectly related to a lapse in import/export control occurred in the Juarez, Mexico/El Paso, Texas border region in 1983, when a SRS in a teletherapy head was accidentally smelted in a metal recycling steel plant. Seventy-five people received high doses of radiation, 814 contaminated houses had to be demolished, several foundries required extensive decontamination, and the cleanup generated 16,000 m<sup>3</sup> of radioactive waste.

As this study went to press, the authors received information that a Texas entity may have used an altered registration certificate in an attempt to acquire a teletherapy quantity of Co-60 from Argentina. These instances of illegal trafficking in SRSs, the Juarez accident, the unsubstantiated Argentine/Texas incident, and the scenarios described in Appendix A provide clear evidence that lapses in import/export control could easily result in a very significant safety or security incident.

#### Key Findings and Recommendations

The key findings of this study are:

- Millions of SRSs have been manufactured and disseminated and SRSs are used worldwide in medicine, manufacturing, construction, oil exploration, consumer goods, research, space exploration, and agriculture.
- Through analysis of past accidents and numerical simulations, security experts are now very concerned that Category 1 and 2 SRSs could be used in a RDD to terrorize and disrupt society.
- There are unwanted SRSs that contain long-lived radionuclides in developing countries least able to mange very long-lived radioactive wastes. For these developing countries, one solution is to transfer the disused SRSs to a developed country with the infrastructure and experienced personnel to properly manage these long-lived radioactive wastes.

- Accidents directly resulting from lapses in import or export control were not identified; however, analogues and scenarios make it clear that SRSs being transferred across international borders are susceptible to unauthorized access through theft or acquisition by false pretenses.
- There is a significant worldwide trade in Category 1 and 2 SRSs.
- During transfer, SRSs are particularly vulnerable to theft, since the sources are in a mobile configuration, the transportation routes are known or can be anticipated, commercial carriers may be responsible for shipping, and shipments may not be adequately guarded.
- Canada and Russia export Category 1 and 2 SRSs without requiring proof that the recipient is authorized by their regulatory authorities to possess such material.
- Category 1 and 2 SRSs can be imported into the U.S. without prior permission. A license to possess a type of SRS carries with it the right to import that type of SRS.

Based on these key findings, this study recommends the implementation of better controls over the intercountry transfer of Category 1 and 2 SRSs.

- 1. Exporting countries should only authorize the export of Category 1 and 2 SRSs if the exporting country is satisfied that the recipient is legitimate.
- 2. Exporting countries should maintain a SRS tracking system.
- 3. Exporting countries should allow reentry of disused SRSs for their return to the manufacturer.
- 4. Importing countries that use Category 1 and 2 SRSs must dedicate the resources necessary to manage the SRSs in a manner consistent with internationally recognized standards.

These recommendations are entirely consistent with the IAEA's guidelines for the import and export of radioactive sources contained in the revised *Code of Conduct on the Safety and Security of Radioactive Sources* that was endorsed by the 136 Member States of the IAEA in September 2003. The authors believe that implementation of these recommendations will greatly reduce the probability of diversion and theft of SRSs for malicious purposes. Finally, actions by individual countries are important, but without adoption by all countries, terrorists and criminals will exploit the weakest link in the SRS life cycle.

## **Definition of Terms**

Alpha Radiation ( $\alpha$  radiation) – the emitting of a particle consisting of two neutrons and two protons.

Becquerel – one Becquerel is equivalent to one atom decaying or disintegrating each second.

Beta radiation ( $\beta$  radiation) – the emitting of electrons from the nucleus.

Curie – one Curie is equivalent to 37 billion  $(3.7 \times 10^{10})$  atoms decaying or disintegrating each second.

Dual-Use – items that have both commercial and military applications.

Fertile Material – material composed of atoms that readily absorb neutrons to produce fissile material. One such material is Uranium-238, which becomes Plutonium-239 after it absorbs a neutron. Fertile material alone cannot sustain a chain reaction. (Institute for Science and International Security website at http://www.exportcontrols.org/index.html)

Fissile Material – material composed of atoms that fission when irradiated by slow or "thermal" neutrons. The most common are Uranium-235 and Plutonium-239. The term is often used to describe plutonium and highly enriched uranium. Uranium-233 is also fissile. (Institute for Science and International Security website at http://www.exportcontrols.org/index.html)

Gamma Radiation ( $\gamma$  radiation) – the emitting of electromagnetic energy from the nucleus of an atom.

Neutron Radiation – the emitting of a neutron from the nucleus.

Orphan source – a radioactive source that is not under regulatory control, either because it was never under regulatory control, or because it was abandoned, lost, misplaced, stolen, or transferred without proper authorization (IAEA, 2003a, draft).

Sealed Radioactive Source - radioactive material that is permanently sealed in a capsule or closely bonded and in a solid form, excluding material within the nuclear fuel cycles of research and power reactors. It also includes any radioactive material released if the source is leaking or broken. (IAEA, 2003a, draft)

Safety - measures intended to minimize the likelihood of accidents with radioactive sources and, should such an accident occur, to mitigate its consequences (IAEA, 2003a, draft).

Security - measures to prevent unauthorized access to, and loss, theft, and unauthorized transfer of, radioactive sources, and measures to protect facilities in which radioactive sources are managed (IAEA, 2003a, draft).

## **Conversion Table**

kilocurie (kCi) ~ 37 terabecquerel (TBq)
curie (Ci) ~ 37 gigabecquerel (GBq)
millicurie (mCi) ~ 37 megabecquerel (MBq)
microcurie (µCi) ~ 37 kilobecquerel (KBq)
nanocurie (nCi) ~ 37 becquerel (Bq)
picocurie (pCi) ~ 37 millibecquerel (mBq)
petabecquerel (PBq) ~ 27 kilocurie (kCi)
terabecquerel (TBq) ~ 27 curie (Ci)
gigabecquerel (MBq) ~ 27 millicurie (mCi)
megabecquerel (MBq) ~ 27 microcurie (µCi)
kilobecquerel (KBq) ~ 27 nanocurie (nCi)
becquerel (Bq) ~ 27 picocurie (pCi)

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## 1. Introduction

Daily and worldwide, radiation is used in agriculture, manufacturing, construction, research, consumer goods, space exploration, teaching, military applications, and medicine. For the treatment of cancer, radiation is an indispensable tool. For example, about half of all cancer patients are treated with radiation (Garcia-Barros, M. et al., 2003). In many cases, radiation is used as a beneficial tool for tasks that would otherwise be difficult or impossible. In the vast majority of these uses, the radiation is from radioactive isotopes, such as Cobalt-60, Cesium-137 and Stroutium-90 (Co-60, Cs-137 and Sr-90), encapsulated in sealed radioactive sources (SRSs).

There are several million SRSs worldwide. While the great majority of these SRSs emit very little radiation, a small percentage of SRSs are highly radioactive. The highly radioactive SRSs are capable of causing death after a few minutes to a day of exposure to the unshielded radioactive material. The International Atomic Energy Agency (IAEA) defines these highly radioactive sources as Category 1 and 2 SRSs. A more detailed discussion of this categorization system is presented in Section 3.2.

There have been a number of accidents involving SRSs as a result of lapses in, or the absence of, regulatory controls. These accidents have contaminated large areas of land, prevented access to portions of cities, created serious social disruptions, and caused many people to receive very high and even fatal doses of radiation. These accidents provide analogues of the possible cleanup costs, health impacts, and societal disruptions that could result from the malevolent use of a Category 1 or 2 SRS in a radiological dispersion device (RDD) or "dirty bomb." In addition, Appendix A illustrates through numerical simulations the potentially devastating consequences of the deliberate misuse of a SRS in a RDD (Appendix A is a stand-alone, classified report).

International concern about the safety and malevolent uses of SRSs was highlighted by a Conference cosponsored by the U.S. and the Russian Federation, hosted by Austria, and organized by the IAEA in Vienna. More than 700 representatives from more than 120 countries attended the March 2003 Conference. The Conference concluded with two major findings. The first was that vulnerable and dangerous SRSs that are not under regulated control, including so-called "orphan" sources, raise serious security and safety concerns and international initiatives should be launched to locate, recover, and secure such orphan SRSs throughout the world. The second finding calls for strengthening national SRS management infrastructures as defined in the IAEA's *Code of Conduct on the Safety and Security of Radioactive Sources* (IAEA, 2003a, draft).

However, it is not just the orphan SRSs that are a security concern. Beck, et al. (2002, p. 9) makes a very important point: "Policy makers should not overlook a basic fact: most countries and terrorists seek to purchase the components they need for developing weapons of mass destruction." Without adequate controls, it may be relatively easy to legally purchase a Category 1 or 2 SRS on the international market under false pretences. Additionally, during transfer, sources are particularly susceptible to theft since the source is in a shielded and mobile configuration, transportation routes are known or anticipatable, commercial carriers may be responsible for shipping, and shipments may not be adequately guarded. Consequently,

government controls on SRS exports and imports are crucial for preventing illicit SRS trafficking. To determine if government controls are currently adequate, Sandia National Laboratories (Sandia) was commissioned by the U.S. Department of State, Office of the Senior Coordinator for Nuclear Safety to assess the adequacy of current import and export controls on SRSs.

## 2. Scope

## 2.1 Scope of Work

This study was commissioned to review the laws and procedures governing the intercountry transfer of SRSs to determine if current practices provide adequate controls. In particular, the Scope of Work required:

- 1. Assessing current notification requirements and practices during each stage of transfer,
- 2. Examining the extent to which the governments of participating IAEA Member States (i.e., countries) control or track these transfers,
- 3. Examining Member State authorization requirements for exports of SRSs,
- 4. Examining the extent to which exporting licenses are contingent on the recipient being authorized to receive the SRS or the importing States having an effective regulatory structure in place to safely and securely manage SRSs,
- 5. Review these issues in detail for three exporter and three importer Member States that represent a broad spectrum of regulatory maturity,
- 6. Determining whether the State will allow the reentry into its territory of disused SRS, and
- 7. Providing examples of how inadequate tracking, notification, and an ineffective regulatory regime in recipient States leads to the loss or theft of SRSs, where possible.
- 8. Although not required by the Scope of Work, this study also presents an estimate of the magnitude of the worldwide trade in IAEA Category 1 and 2 SRSs.

Detailed information on the protocols used by different countries to govern the import or export of SRSs was not available at the time the scope of work was defined. Consequently, the planned tasks were more difficult than anticipated for three reasons: (1) the laws in less developed countries were not readily accessible; (2) it was especially difficult to access the regulations governing the export of SRSs from the Russian Federation; and (3) the laws in the developed countries are complicated, addressing such issues as dual use, exemptions for low activity sources (e.g., smoke detectors), taxation issues, safety issues, divisions of responsibilities between various organizations, and nuclear non-proliferation issues.

This report is written for both non-technical and technical audiences. The first type of reader needs to know whether controls adequate or not. For this reader, the authors present a number of summary tables and an Executive Summary. The technical audience needs access to the details behind the summaries. Details are important because they are required by the scope of work, they show that altering protocols may be complicated, and because one country's export or import control laws may be of interest to another country that is considering altering its export or import control laws.

## 2.2 Overview of this Study

This study reviews the laws of six countries governing the export or import of SRSs. As part of this analysis, the following subjects were examined:

- Use of Sealed Radioactive Sources (Section 3.1),
- Number and Categorization of Sealed Radioactive Sources (Section 3.2),
- Production and Distribution of Sealed Radioactive Sources (Section 3.3),
- Properties of Most Commonly Used Radionuclides (Section 3.4),
- Magnitude of the Worldwide Trade in Sealed Radioactive Sources (Section 3.5),
- Accidents Involving Sealed Radioactive Sources (Section 3.6),
- Selection of Exporting and Importing Countries (Section 3.7),
- Detailed Review of the Export Regulations of Three Countries (Sections 4.1 4.3),
- A detailed Review of the Import Regulations in Three Countries (Sections 5.1 5.3),
- Lapses in Import/Export Control (Section 6), and
- Summary and Recommendations (Section 7).

## 3. Background

## 3.1 Use of Sealed Radioactive Sources

SRSs are widely available and used daily in a range of applications (Harris, 1994). SRSs have enhanced human lives and contributed to global economic development for over half a century. "Sealed radioactive source" means radioactive material that is permanently sealed in a capsule or closely bonded and in a solid form, excluding material within the nuclear fuel cycles of research and power reactors. It also includes any radioactive material released if the source is leaking or broken (IAEA, 2003a, draft).

The majority of SRSs have the following characteristics:

- They are small, typically occupying less than  $15 \text{ cc} (1 \text{ inch}^3)$ ,
- They are stainless steel capsules,
- They are airtight,
- They are durable, and
- They appear harmless.

SRSs may contain one of hundreds of radioisotopes (e.g., Co-60, Cs-137, Ir-192, etc.). The properties of the most commonly used radioisotopes are summarized in Section 3.4. SRSs are very diverse with activities that range from less than 1 MBq (~ 27  $\mu$ Ci) to several PBq (tens of kCi). However, most sources have activities less than four MBq (100 mCi) (Harris, 1994). Depending on the material used in the source, SRSs may emit neutrons and/or alpha, beta, or gamma radiation. The half-lives of the typical radioisotopes range from 74 days for Ir-192 to 1,600 years for Radium-226 (Ra-226).

## 3.1.1 Medical Applications

Hospitals and medical clinics are among the largest users of SRSs. Radiation is an indispensable tool for the treatment of cancer, and approximately half of all cancer patients receive some form of radiation treatment. These treatments may be provided by SRSs in teletherapy machines, multibeam teletherapy machines, and by brachytherapy. In teletherapy, there is no direct contact between the SRS and the tumor; with brachytherapy, the SRS is physically implanted in immediate contact with the tumor. Photographs of these typical medical applications are provided by the IAEA (2002b).

Teletherapy machines contain between 0.04 and 5 PBq (1 and 150 kCi) of Co-60, with 0.16 PBq (4 kCi) being typical. The multibeam teletherapy machines (gamma knife) contain between 0.16 and 0.37 PBq (4 and 10 kCi) of Co-60 (IAEA, 2003b). The cobalt and cesium teletherapy sources are some of the highest activity SRSs in public use. Co-60 is the most common radionuclide used in teletherapy, although some Cs-137 sources are also in use. The IAEA states

that there are more than 10,000 radiotherapy units for medical care in use worldwide (IAEA, 2002a). Electron beam techniques can replace radioactive sources for therapies, with the added advantage that the units can be shut off, thus eliminating many of the legacy concerns associated with high activity SRSs.

Until the 1950s, the only significant SRSs produced were the Ra-226 SRSs for brachytherapy. Most of the Ra-226 SRSs have been replaced by Co-60, Cs-137, and Ir-192 (IAEA, 1999). In some cases, the developed countries donated the older Ra-226 brachytherapy SRSs to medical institutions in developing countries. Because Ra-226 has a half-life of 1,600 years, and the radium is in a water-soluble form, it is very difficult to safely dispose of unwanted Ra-226 SRSs. The charity efforts of the 1950's and 1960's inadvertently placed the Ra-226 SRSs in developing countries least able to mange the very long-lived radioactive wastes. For the developing countries, one solution is to transfer the disused SRSs to a developed country that has the infrastructure and experienced personnel to properly manage these long-lived radioactive wastes. This study will determine if the developed (exporting) countries being reviewed will allow reentry of disused SRSs.

Blood irradiators are also an important medical application for SRSs. Blood irradiators contain Cs-137 or Co-60 SRSs, with Cs-137 being dominant. Blood irradiators typically contain 0.04 to 0.2 PBq (1 to 5 kCi) of Cs-137. It has been estimated that there are 400 to 500 blood irradiators in the U.S. and about half of those (200 to 250) are no longer in use (Archuleta et al., 2002). As discussed below, industrial irradiators are used to sterilize medical equipment.

## 3.1.2 Research and Education Applications

A wide variety of radionuclides in the form of SRSs are used in education and research. Table 4-1 provides a sample listing of the types of open and sealed radionuclides used in research and medicine. One of the more common research applications is to use neutron-producing Americium-241/beryllium (Am-241/Be) sources or neutron-producing Plutonium-239/Be (Pu-239/Be) sources to measure the moisture content of agricultural soils. During the 1960s, gamma irradiators containing quantities of Co-60 or Cs-137 were widely employed for research purposes. In some instances, SRSs were purchased for specific research projects and then placed in ongoing storage (i.e., set aside) after the projects were completed.

## 3.1.3 Industrial Applications

Ir-192 is typically used in industrial radiography, such as the non-destructive imaging of castings or pipe welds where the use of x-rays is not feasible. Large neutron and gamma sources are used in mining and oil and gas "well logging." These neutron sources contain either Pu-239/Be or Am-241/Be; there are also a few Ra-226/Be neutron sources. Am-241/Be neutron sources have typical activities of 0.8 TBq (20 Ci) (IAEA, 2003b). The U.S. Am-241/Be neutron sources have maximum activities up to 2.5 TBq (60 Ci) (Harris, 1994, B-10). In oil-rich developing countries, industrial applications (e.g., oil "well logging" and radiography) may exceed medical applications. The IAEA estimates that about 12,000 SRSs for industrial radiography are supplied annually (IAEA, 2002a). The most common industrial use of SRSs is in level and

thickness gauges. SRSs are also used in industry for level and density control, flow rate measurement, belt weighing, static elimination, column scanning, and moisture measurement. If these gauges are not removed when a factory is closed, they can, and have, ended up in metal recycling facilities (IAEA, 1999a).

Soil density gauges are widely used to determine the density of compacted soils at construction sites. These density gauges contain Cs-137 sources (to determine the soil density), and neutron-producing Am-241/Be or Pu-239/Be sources to determinate the moisture content of the soils. According to a story on the CNN website ("Radiation Detected in Post September 11 World," August 19, 2003), there are some 20,000 soil density gauges in use in the U.S. and approximately one of these units is stolen from construction/engineering companies every week. Fortunately, the Cs-137 and Am-241/Be source in soil density gauges are not Category 1 or 2 SRSs.

Radioisotope thermoelectric generators (RTGs) use heat generated by decay of radioactive isotopes to produce electrical power. RTGs have no moving parts and can operate for over a decade without refueling. They are used as a power supply where frequent maintenance or refueling is expensive or impossible. The U.S. has manufactured approximately 136 terrestrial RTGs (unpublished U.S. Department of Energy data) and the Former Soviet Union has manufactured about 900 terrestrial RTGs (Rylov, M., 2000).

Most terrestrial U.S. RTGs are fueled with Sr-90. The largest known U.S. RTG (the BUP-500) was originally fueled with 25 PBq (685 kCi) of Sr-90; however the typical U.S. RTG contains about 2 PBq (50 kCi) of strontium. In many cases, the Sr-90 is in a ceramic titanate (SrTiO<sub>3</sub>) form that also produces bremsstrahlung x-rays. Spacecraft may contain Pu-238-fueled RTGs as power supplies for deep space applications.

Industrial irradiators containing Co-60 or Cs-137 SRSs are used to sterilize medical products, as well as meat, fresh vegetables, and other foods. There are about 300 irradiator facilities in operation for industrial applications (IAEA, 2002a). A single industrial irradiator facility may contain over 100 PBq (millions of curies) of Co-60 in arrays of SRSs.

Co-60, Cs-137, and Ir-192 are all employed to produce gamma radiation for radiography, teletherapy, blood irradiation, and industrial irradiators. Ir-192 has a very high specific activity, and a correspondingly short half-life (74 days). Because of its high specific activity, Ir-192 is now favored for radiography. Because of its short half-life, Ir-192 is not typically used for teletherapy or irradiators (refueling multiple times per year would be impractical). Cs-137 has a half-life of approximately 30 years, which is ideal from a refueling perspective. However, the Cs-137 chloride inside the SRS is in a powder form that is easily dispersed, should the SRS be accidentally or deliberately ruptured. Despite its shorter half-life (five years), Co-60 metal is now the preferred isotope for use in teletherapy equipment and industrial irradiator facilities, although Cs-137 remains the major radionuclide used in blood irradiators.

# 3.2 Number and Categorization of Sealed Radioactive Sources

While there is no accurate accounting of SRSs, the IAEA estimates that millions exist worldwide (IAEA, 2002a). Most SRSs are low in activity; however, there is a significant number of high activity SRSs (IAEA, 2002b). The IAEA has categorized SRSs into five categories with respect to possible health effects. This categorization allows the IAEA and its Member States to apply a graded approach to management of SRSs. A few minutes of exposure to an unshielded Category 1 SRSs can cause death. Category 2 sources can also cause death, if the exposure times are on the order of a few hours to a day. On the other extreme are the Category 5 SRSs that are benign (such as "tritium lights" used in some wristwatches). Category 3 and 4 SRSs are between benign and high activity. Category 3 and 4 sources can cause some adverse health effects under certain unique circumstances (IAEA, 2003b).

The IAEA categorization is based on exposure to an unshielded but intact SRS. Some RDD dispersion mechanisms could cause significant aerosolization of the radioactive materials in a SRS (e.g., Appendix A presents such scenarios). Aerosolization would decrease the activity thresholds for some radionuclides. For example, an intact, alpha-emitting SRS produces little contact dose and might not rank as a Category 1 or 2 SRS in the IAEA system, yet if the alpha-emitting SRS were aerosolized in a RDD, the dose consequence might be equal to the dose consequence for a Category 1 or 2 SRS.

The IAEA states that the Category 1 and 2 sources are of greatest concern from safety and security perspectives (e.g., see IAEA (2003a draft), items 23, 24, and 25). The Category 1 and 2 SRSs typically involve only a few radionuclides, typically Co-60, Cs-137, and Ir-192; however, there are a few notable Category 1 and 2 applications that employ Sr-90, Pu-239/Be, and Am-241/Be (IAEA, 2003b). Category 1 SRSs/applications include RTGs, irradiators, teletherapy, and fixed multibeam teletherapy (gamma knife). Category 2 SRSs/applications include industrial gamma radiography and high/medium dose-rate brachytherapy.

These Category 1 and 2 sources can also be divided between those that are disused, and those in use. The IAEA estimates that about 20% of all SRSs are disused (IAEA, 1991, pages 11 and 25) and as a specific example, it is estimated that about one-half of all Cs-137 blood irradiators in the U.S. are disused (Archuleta, et al., 2002). Spent or disused SRSs often comprise the majority of radioactive wastes generated in most of the IAEA's 136 Member States. Although termed "spent," many of these radioactive sources are long-lived and many still have very high levels of residual radioactivity (IAEA, 1999). The absence of other nuclear activities in most developing countries may actually enhance the risk associated with the disused radioactive sources, since these countries often lack the infrastructures and experienced personnel required for safe waste management.

For the developing countries, one solution is to return the disused SRSs to the developed country that initially produced the SRSs, because the developed countries have the infrastructure and experienced personnel to properly manage these radioactive wastes. This study will determine if the exporting countries being reviewed will allow reentry of disused SRSs.

# 3.3 Production and Distribution of Sealed Radioactive Sources

Eight countries produce the majority of radionuclides used in SRSs that are distributed worldwide. These countries are:

- Argentina,
- Belgium,
- Canada,
- France,
- Netherlands,
- Russia,
- South Africa, and
- The U.S.

A small share of the world market is provided by other countries, such as Australia, South Korea, China, India, and Japan (Ferguson et al., 2003, pp. 22-25). The distribution network for SRSs and devices containing SRSs is complex; Ferguson et al., (2003) provides a comprehensive overview of this network.

## 3.4 Properties of Most Commonly Used Radionuclides

The IAEA provides an excellent overview of the characteristics of the most commonly used radionuclides in SRSs; which are Co-60, Cs-137, Sr-90, Ir-192, Am-241 and Ra-226. The following summary is based on IAEA (2000).

Co-60 decays by emission of a beta particle and two gamma photons to a stable nickel isotope. Metallic cobalt pellets may be welded inside a stainless steel SRS, or the metallic cobalt may be nickel-plated and used directly. The metal is not water soluble and is stable in air. Co-60 has a half-life of 5.3 years. Co-60 produced from pure cobalt-59 is free of other radionuclides and the gamma radiation is at 1.17 and 1.33 MeV.

Cs-137 is a byproduct of the fissioning of nuclear fuel. Cesium is very reactive and it is an alkali metal similar to potassium and sodium. Cesium chloride powder is often welded inside stainless steel SRSs. Cesium-137 is a gamma-emitter (0.66 MeV) with a half-life of 30.2 years.

Ir-192 has a half-life of 74 days, and it decays by emission of beta particles and gamma photons to stable platinum and osmium. Iridium metal is not water soluble and will not oxidized in air.

Sr-90 is also a byproduct produced of the fissioning of reactor fuel and its half-life is 28.6 years. Sr-90 decays by beta emission to Yitrium-90, which has a half-life of 64 hours. Both nuclides

are pure beta emitters. Strontium is very reactive chemically and an alkali earth metal similar to calcium. In many cases, the Sr-90 is sintered into a durable ceramic titanate ( $SrTiO_3$ ) form that also produces bremsstrahlung x-rays.

Ra-226 is an alpha emitting naturally occurring radioactive material that has a half-life of 1,600 years. The Ra-226 decay chain includes eight radioactive daughters. Including the daughters, a single Ra-226 atom produces five alpha particles, many high and low energy gamma photons, and beta particles. Radium is a very reactive alkali earth metal. In SRSs radium is always used in the form of salts (e.g., chloride or carbonate salts). The Ra-226 salts used in SRSs are soluble in water. The management of disused and unwanted Ra-226 SRSs is difficult because radium is long-lived, produces many forms of ionizing radiation and is water soluble.

Am-241 is used in oxide forms and has properties similar to the rare earth metals. Oxide Am-241 powder is mixed with beryllium powder and sintered to a ceramic-like product that produces neutrons and is stable in air and water. Am-241 has a half-life of 432 years.

# 3.5 Magnitude of Worldwide Trade in Radioactive Sources

## 3.5.1 Magnitude of Worldwide Shipments of Radioactive Materials

It has been estimated that, worldwide, between 18,000,000 and 38,000,000 packages of radioactive material are shipped each year (IAEA, 2002c). This 2002 IAEA publication on transportation of radioactive materials cites a 1987 study – therefore the estimate of 18,000,000 to 38,000,000 radioactive packages is probably on the low side. This number is the grand total of inter- and intra-country shipments that include the spectrum from "open" medical isotopes shipped to hospitals, to a radiography SRS moved from the shop to the job site, to nuclear wastes being moved from hospitals to disposal facilities.

## 3.5.2 Magnitude of Worldwide Trade in Radioactive Sources

Firm numbers describing the total annual intercountry transfer of civilian Category 1 and 2 SRSs are not available. Accordingly, this section develops an order-of-magnitude estimate of the significance of the worldwide trade in Category 1 and 2 SRSs based on published summary statistics presented above, stated assumptions, and best professional judgment. Where the literature provided a range of values, the larger number was used to offset information that is not available. For example, the authors made upper bound estimates of the type of radionuclide, the refueling frequency, and the return rate of teletherapy SRSs to offset the uncertainty in the statistic that there are *more than* 10,000 radiotherapy units in use worldwide.

#### 3.5.2.1 Assumptions in Estimating Number of Shipments

The author's estimate of the magnitude of the worldwide trade in Category 1 and 2 SRSs is based on the following assumptions.

<u>Category 1 and 2 SRSs</u> Category 1 and 2 SRSs/devices include: teletherapy machines, high- and medium-dose brachytherapy devices, RTGs, industrial/food irradiator machines or facilities, blood irradiators, and radiography sources (IAEA, 2003b). It is assumed that all shipments of the Category 1 and 2 sources are intercountry (that is, there are no shipments internal to a country).

<u>Teletherapy Machine</u> There are more than 10,000 radiotherapy units for medical care in use worldwide. Teletherapy machines are typically fueled with either Co-60 or Cs-137. The Co-60 machines require refueling every five to 10 years and the Cs-137 machines can operate over 30 years on the original fuel. The authors assume all teletherapy machines contain Co-60 and each machine is refueled every five years (i.e., 20% of the machines are refueled each year).

It is further assumed that each Co-60 refueling requires two intercountry shipments (one with fresh cobalt and one returning disused cobalt), and that based on Appendix II of IAEA (2003b), the returning sources remain in Category 1 or 2. This is an overestimate because many disused teletherapy sources remain in the country of use. IAEA (2002b) discusses the problem of older Co-60 and Cs-137 teletherapy machines and the inability of the owner to return the SRS to the manufacturer, either because the early manufacturers are out of business, the older Co-60 or Cs-137 sources cannot comply with current transportation standards, or because owners cannot afford transportation/disposal costs.

<u>High- and Medium-Dose Brachytherapy Devices</u> The IAEA estimates that there are currently about 1,500 high dose rate, remote after-loading Ir-192 machines involving 5,000 source changes annually<sup>2</sup>. As each old source is returned, there are about 10,000 source shipments annually. However, the strength of the returning Ir-192 sources is reduced and the returning sources no longer qualify as Category 1 or 2.

The IAEA estimates that there are less than 100 medium dose rate Cs-137 machines, and because the manufacture has ceased, this number is static.<sup>3</sup> Because the Cs-137 machines can operate over 30 years on the original fuel, and because the manufacturer has ceased production, the authors assume, on average, three shipments of retired Cs-137 machines per year.

In addition to the 60 Ralston machines, the Former Soviet Union produced 300 AGAT Co-60 high-dose rate machines (200 of these are in Russia; the balance are probably in Former Soviet Union Republics<sup>4</sup>). For the 360 machines, the authors make the simplifying assumptions that the Co-60 machines are refueled every five years. As each old source is returned, there are about 144 source shipments annually. However, based on Appendix II of IAEA (2003b), the strength of the returning Co-60 sources is reduced and the returning sources no longer qualify as a Category 1 or 2 SRS.

<sup>&</sup>lt;sup>2</sup> Personal communication with C. Victor Levin, Section Head: Applied Radiobiology and Radiotherapy, NAHU, IAEA on September 11, 2003.

<sup>&</sup>lt;sup>3</sup> Personal communication with C. Victor Levin, Section Head, Applied Radiobiology and Radiotherapy, NAHU, IAEA on September 11, 2003.

<sup>&</sup>lt;sup>4</sup> Personal communication with S. Vatnitsky, Ph.D., Dosimetry and Medical Radiation Physics Section, Division of Human Health, IAEA on September 11, 2003 (referenced an article in Russian in Medical Physics (2002, N3, p 43-46)).

<u>RTGs</u> There are approximately 900 RTGs in the Former Soviet Union Republics, but there is no real civilian trade in RTGs.

<u>Industrial/Food Irradiator Facilities</u> As previously cited, there are about 300 irradiator facilities in operation for industrial applications.

Industrial irradiator facilities, like teletherapy machines, are typically fueled with Co-60 or Cs-137. The authors assume all irradiator facilities contain Co-60 and each facility is refueled every five years. However, unlike teletherapy machines, it is assumed that only one shipment occurs every five years, and the disused sources remain in the irradiator facility until the end of the useful life of the facility (say 30 + years).

<u>Blood Irradiators</u> There are 400 to 500 Cs-137 blood irradiators in existence in the U.S. and 200 to 250 of these are no longer in use (Archuleta et al., 2002). It is not known how many blood irradiators are in use worldwide. Two ways to estimate the number of irradiators worldwide are (a) assume the number of blood irradiators is proportional to the population of a country, or (b) assume the number is proportional to gross domestic product of a country. The U.S. has 5% of the world's population,<sup>5</sup> and produces 21% of the world's gross domestic product.<sup>6</sup> Because the number of irradiators is probably based more on ability to purchase than on medical need, the number of blood irradiators worldwide was estimated based on gross domestic product. Since the U.S. produces 20% of the worlds GDP and the U.S. has about 250 blood irradiators in use, we estimate there are 1,250 blood irradiators in use in the world.

If Cs-137 blood irradiators are replaced every 30 years, then about 40 new sources are shipped each year on average (1,250/30). It is further assumed that each Cs-137 blood irradiator replacement requires two intercountry shipments (one new and one returning for 80 shipments per year), and that based on Appendix II of IAEA (2003b); the returning sources remain in Category 1 or 2.

<u>Radiography Sources</u> As noted earlier, there are about 12,000 industrial sources for radiography supplied each year.

#### 3.5.2.2 Summary of Estimate

Table 3-1 presents an order-of-magnitude estimate of the number of Category 1 and 2 SRSs transferred annually. The grand total, 21,215, represents about one-tenth of 1% of the 18,000,000 to 38,000,000 packages of radioactive material shipped each year.

A recent U.S. General Accounting Office (GAO) study surveyed all of the IAEA Member States with respect to their control of SRSs and asked broad questions about the numbers of SRSs imported and exported (GAO, 2003). The survey did not separate Category 1 and 2 sources from SRSs fitting into Categories 3, 4 and 5 and only 49 of the 136 IAEA Member States replied to the survey. Canada, the major exporter of Co-60, was one of the 49 countries that participated in the Survey. However, many countries with significant economies, or significant roles in the

<sup>&</sup>lt;sup>5</sup> 273 million people out of 5,996 million people, from

http://www.photius.com/wfb1999/rankings/population\_0.html

<sup>&</sup>lt;sup>6</sup> \$10,082 billion out of \$47,000 billion, from http://www.wallstreetview.com/GDPRankings.html

Category 1 and 2 Application	Annual Number of SRSs In Transit
Teletherapy	4,000
High and medium brachytherapy	5,075
RTGs	0
Food/Industrial Irradiators	60
Blood Irradiators	80
Radiography Sources	12,000
Total (Order-of-Magnitude)	21,215

#### Table 3-1. Estimate of Worldwide Trade in Category 1 and 2 SRSs

worldwide trade of SRSs did not participate, including China, India, Russian Federation, South Africa, and the United Kingdom.

The GAO survey revealed that (for the 49 Member States that did participate) approximately 3,200 Co-60 sources were imported/exported in calendar year 2002 (GAO, 2003, p. 58). This study estimates that about 4,132 Category 1 and 2 SRS Co-60 SRSs were transferred annually from all countries. For Ir-192, the GAO Survey showed about 8,000 Ir-192 sources were imported/exported and study estimates that about 17,000 Ir-192 SRSs were transferred annually (all countries).

Our study was based on simplifying assumptions and summary statistics from various IAEA and U.S. publications. The GAO results are based on Survey responses from a number of countries. As an independent, but approximate comparison, the numbers for Co-60 (3,200 vs. 4,132) and Ir-192 (8,000 vs. 17,000) are comparable.

Based on published summary statistics, a number of assumptions presented in this report, and best professional judgment, this report estimates that between 10,000 and 100,000 Category 1 and 2 SRSs are shipped between countries annually. On an average day, there are tens to possibly hundreds of intercountry transfers of Category 1 and 2 SRSs. With such large numbers there is significant opportunity for unauthorized access through diversion, theft, or acquisition by false pretenses.

## 3.6 Accidents Involving Sealed Radioactive Sources

There have been large numbers of accidents involving SRSs as a result of lapses in, or the absence of, adequate regulatory controls. The U.S. Nuclear Regulatory Commission (NRC) database notes more than 2,300 reports of SRSs found or incorporated in scrap metal (IAEA, 1999, p. 4).

Accidents with significant health consequences have occurred with regularity around the globe, including Juarez, Mexico; Goiânia, Brazil; Istanbul, Turkey; Tbilisi, Georgia; and Bangkok, Thailand. In any given year, there are approximately one to three serious accidents, as

summarized by the IAEA (1999, pp. 14-15). Some of these accidents caused widespread social disruptions, denied access to large areas of cities, contaminated portions of land, and caused many people to receive very high, and even fatal doses of radiation. As an illustration, two of these accidents are summarized below.

In January of 2002, three lumberjacks were hospitalized in Tbilisi, Georgia after finding two Category 1 uncontrolled PBq (30 kCi) Sr-90 SRSs in a forest. The powerful Sr-90 SRSs were from abandoned Soviet-era RTGs. Hundreds of villagers living nearby were thrown into panic. With international assistance, the two highly radioactive sources were recovered by the IAEA in February of 2002. Six months later, two of the three men remained hospitalized because of the massive doses of radiation they received. International press coverage focused on both the health hazards of uncontrolled SRSs, and the potential use of the Sr-90 SRSs for making a dirty bomb.

In Goiânia, Brazil in 1987, a teletherapy machine containing a Category 1 50 TBq (1,300 Ci) Cs-137 SRS was stolen from a closed medical clinic and deliberately cut open (this is classified as a accident because the individuals did not know they were releasing the Cs-137). Children were allowed to play with the glowing material inside. Four people died within days, several hundred suffered health effects, and public panic ensued. One hundred and twelve thousand people sought medical attention (NCRP, 2001, p. 62). Over several years, contaminated soils and many buildings had to be cleaned up, generating thousands of cubic meters of radioactive wastes and costing millions of dollars (IAEA, 1988). There was economic discrimination against both people and products from Goiânia with a 20% decrease in sales, and a dramatic decline in tourism (GAO, 2003).

Such accidents provide analogues of the very serious damages that might be deliberately inflicted by terrorists on U.S. domestic and international interests. Furthermore, it is the IAEA Category 1 and 2 sources that pose the most significant risk, and therefore are given the highest priority in this study.

Sources transferred across international borders are particularly susceptible to unauthorized access through diversion, theft, or the use of false pretenses. Because of this concern, this study was undertaken to determine the current status of laws and procedures governing intercountry transfer of SRSs to determine if these current practices provide adequate controls. To match the monetary scope of work, the laws of three importing and three exporting countries were reviewed. The selection of these six countries is detailed in the next section.

## 3.7 Selection of Exporting and Importing Countries

There are approximately 136 Member States in the IAEA and six were selected for a detailed review. Criteria for selecting the three importing countries and three exporting countries from the list of approximately 136 included:

- Sampling a cross-section of developed and developing countries, and
- Sampling a cross-section of continents (Americas, Europe, Asia, and Africa).

After a number of discussions with the IAEA, the staff at Sandia, and the staff in the Office of the Senior Coordinator for Nuclear Safety, the following countries were selected:

#### **Exporting Countries:**

- Canada
- Russia
- South Africa

#### Importing Countries:

- Egypt
- Philippines
- The U.S.

The exporting countries are reviewed in Section 4, followed by a review of the importing countries in Section 5.

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# 4. Exporting Countries

This chapter presents a detailed review of the laws governing the export of SRSs from Canada, Russia, and South Africa. Each country is reviewed using a consistent format that covers: the introduction and nature of exports; the regulatory requirements associated with the export of SRSs; how the regulations address specific questions posed in the statement of work; and a table summarizing the key aspects of the export regulations.

## 4.1 Canada

## 4.1.1 Introduction/Nature of Exports

Definitive information on the number and total curies of SRSs exported annually could not be identified; however, meaningful evidence was located and is summarized in this section.

The U.S. receives the majority of the Canadian exports. Canadian exports of nuclear-related materials or technologies include CANDU reactors and equipment, pressurized water reactor (PWR) equipment, uranium conversion materials, and radioactive elements and isotopes. In *Nonproliferation Export Controls in Canada*, Jones (2002) reports that 1999 exports from Canada of radioactive elements and isotopes totaled \$132 million Canadian. Additional information concerning radioactive materials exported from Canada is available on *The Canadian Nuclear FAQ website* (Whitlock, 2003).

Canada is reported to produce 85% of the world's Co-60 for medical and industrial uses. Medical Co-60 is produced in a research reactor at Atomic Energy of Canada Limited's Chalk River site, while industrial Co-60 is produced in select CANDU power reactors (Whitlock, 2003). The major producer of Co-60 in Canada is MDS<sup>™</sup> Nordion<sup>™</sup>. Other SRSs produced by MDS<sup>™</sup> Nordion<sup>™</sup> include doubly-encapsulated Cs-137 used in blood irradiators. Over one-half of the Co-60 therapy machines and medical sterilizers in use throughout the world were built in Canada (Whitlock, 2003). The major Canadian manufacturer of these units is also MDS<sup>™</sup> Nordion<sup>™</sup>.

Canada is reported to produce 60% of the world's supply of Mo-99, which decays to Tc-99m and is used in nuclear medicine (Whitlock, 2003). Approximately 4,000 procedures using Tc-99m are performed daily in Canada and 40,000 per day are performed in the U.S. (Whitlock, 2003). The Canadian producer of Mo-99/Tc-99m is also MDS<sup>™</sup> Nordion<sup>™</sup>. This information on Mo-99/Tc-99m provides general information, as Mo-99/Tc-99m used for nuclear medicine purposes is in a solution form and is not a sealed source.

Table 4-1 compiles the nuclear-related goods produced by MDS<sup>™</sup> Nordion<sup>™</sup> at their Kanata, Ontario location and exported from Canada. MDS<sup>™</sup> Nordion<sup>™</sup> is a manufacturer, processor, and producer of chemical products, pharmaceuticals, and radioisotope-containing products used for health care and other industrial applications. MDS<sup>™</sup> Nordion<sup>™</sup> exports to countries throughout

Product	Use
Barium Carbonate (C-14)	Biochemical, biological, and chemical research
Cobalt-60 (Co-60)	Gamma sterilization of medical products
Cobalt chloride (Co-57)	Standard source for calibration, industrial tracer applications, <i>in vitro</i> diagnostic kits, diagnostic imaging
Gallium chloride (Ca-67)	Medical diagnostics
Hydrochloric acid (Cl-36)	(No use given.)
Indium chloride (In-111)	Medical diagnostics
Iodine-125 (I-125)	Clinical and research applications
Iridium-192 (Ir-192)	Industrial radiography
Nickel chloride (Ni-63)	Industrial applications
Sodium iodide (I-123)	Diagnostic imaging (brain, heart, thyroid)
Sodium iodide (I-125)	Clinical lab tests, brachytherapy, research applications
Sodium iodide (I-131)	Medical (thyroid imaging and therapy)
Sodium molybdate (Mo-99)	Nuclear medicine
Strontium chloride (Sr-82)	Heart imaging
Thallium chloride (Tl-201)	Heart imaging
Thallous chloride (Tl-201)	(No use given.)
Xenon (Xe-133)	Brachytherapy and lung scanning
Ferrous chloride (Fe-59)	(No use given.)
Gammacell® (Cs-137 in CsCl)	Clinical blood and research irradiators

#### Table 4-1. Examples of Canadian exports produced by MDS™ Nordion™

Reference: Industry Canada (2002), *Canadian Company Profiles*. Canadian Company Capabilities, MDS™ Nordion™ company profile. Website : http://strategis.ic.gc.ca/cgi-bin/sc\_coinf/ccc/cccsrch; Updated October 22, 2002.

the world, including the U.S. and countries in Europe, Africa, South America, Asia, and the Middle/Near East. The Therapy Systems Division alone of MDS<sup>™</sup> Nordion<sup>™</sup> is reported to have annual total export sales of \$25 to \$50 million Canadian (Industry Canada, 2002). Total export sales for all divisions of MDS<sup>™</sup> Nordion<sup>™</sup> can be expected to be much higher.

An additional company exporting radioactive materials from Canada is Amersham Health Inc., which exports \$25 to \$50 million Canadian of diagnostic imaging products (Industry Canada, 2002).
## 4.1.2 Regulatory Requirements

There are three groups involved in controlling the export of materials from Canada discussed in the following sections:

- The Canadian Department of Foreign Affairs and International Trade (DFAIT),
- The Canadian Customs and Revenue Agency (CCRA), and
- The Canadian Nuclear Safety Commission (CNSC).

#### 4.1.2.1 Department of Foreign Affairs and International Trade

Under the Export and Import Permits Act (EIPA, R.S., c. E-17, s.1.), the DFAIT is responsible for establishing trade controls. An export permit from the DFAIT is required if the material is considered controlled goods, which are goods on one of the following lists:

- The Area Control List (ACL),
- The Export Control List (ECL), or
- The Automatic Firearms Country Control List.

The ACL is routinely updated by the DFAIT; only the countries of Angola and Burma (Myanmar) were listed on the ACL in 2002. An export permit must be obtained to ship any goods, including SRSs, to a country on the ACL. In addition to countries on the ACL, exports to countries under embargo by the United Nations may be prohibited.

An export permit must also be obtained for the export of any goods on the ECL. There are eight groups of goods on the *ECL*. Of these eight, three groups are relevant to the export of SRSs: Group 3, *Nuclear Non-Proliferation List;* Group 4, *Nuclear-Related Dual-Use Substances;* and Group 5, *Miscellaneous Goods* (DFAIT, 2003).

Group 3 of the ECL is aimed at controlling the export of materials and equipment that could potentially be used to construct nuclear weapons. The export of SRSs with nuclear materials listed in Group 3 of the ECL would require an Export Permit from the DFAIT. Isotopes that may be present in SRS and fall under Group 3 classification include:

- Item 3001, Special fissionable material, which includes all plutonium isotopes in any alloy or compound, with the exception of Pu-238 in pacemakers, and U-233 and U-235 in all alloys and compounds.
- Item 3002, Source material, including natural uranium, depleted uranium, and thorium.
- Item 3012, Tritium, including mixtures and compounds with a tritium to hydrogen ratio greater than 1:1000.

The purpose of Group 4 of the ECL is to provide additional controls for materials that may be used for both a nuclear weapon-related purpose and a non-weapon use. Radionuclides included in Group 4 that may be present in some SRSs include the following.

• "Alpha-emitting radionuclides having an alpha half-life of 10 days or greater but less than 200 years, compounds or mixtures containing any of these radionuclides with a total alpha

activity of 37 GBq/kg (1 Ci/kg) or greater, and products or devices containing any of the foregoing except a product or device containing less than 3.7 GBq (100 mCi) of alpha activity" (CG 2000-06-21, part B.1.1.1.). An SRS containing Pu-238 would fall under both Groups 3 and 4 of the Canadian ECL.

• "Radium-226, radium-226 compounds, or mixtures containing radium-226, and products or devices containing any of the foregoing, except medical applicators and a product or device containing not more than 3.7GBq (10 mCi) of radium-226 in any form" (CG 2000-06-21, part B1.1.16.).

Group 5 of the ECL includes Item 5400, *Foreign Origin Goods*. An export permit must be obtained for goods that originate in the United States, are shipped to Canada, and eventually shipped to another country. This requirement applies to goods that are "further processed or manufactured outside the United States so as to result in a substantial change in value, form or use of the goods or in the production of new goods" (DFAIT, 2003). In addition to the Canadian export permit, the documentation must include a certified copy of the United States *Shipper's Export Declaration*. The export of an SRS from Canada might fall under Group 5 if, for example, the original radioactive material was produced in the U.S., then shipped in bulk form to a manufacturer in Canada, where it was formed into a doubly-encapsulated source. Goods that originate in the U.S. are shipped to Canada, and then shipped back to the U.S. are not included under Group 5.

In April 2002, Item 5505, "Goods for Certain Uses", was added to Group 5 of the Canadian ECL. This addition included a measure that could be used as a "catch-all" control because it was believed that, in light of recent developments in terrorist activities, the ECL could never include all the goods and technologies that could pose a security risk (Jones, 2002). Item 5505 is aimed at certain countries not party to multilateral export controls and does not apply to a number of countries, including (but not limited to) the United States, the United Kingdom, Australia, Germany, and Russia. Under Item 5505, the exporter must identify the end-use of proposed exports and may be required to obtain an export permit if the Government believes the material may be eventually used for unacceptable activities (Jones, 2002).

The Export and Import Controls Bureau (EICB) is part of the DFAIT and includes an Export Controls Division (EPE) that administers the export controls required under the EIPA. The various sections of the EPE assess export permit applications for control status and review documentation. Because the EPE may draw upon various experts from several DFAIT divisions and other Departments of the Canadian Government to individually assess declarations, the review process may take several weeks. Supporting documentation required by the Permit Section includes the following for export permit applications (DFAIT, 2003).

- International Import Certificates (IICs) are requested by the Canadian exporter and are obtained by the importer. The purpose of an IIC is to notify an importing country of a proposed shipment. The IICs are usually valid for six months and are submitted to the Export Controls Division of the DFAIT.
- Delivery Verification Certificates (DVs) are usually issued by the import control authorities in the receiving country and are used to certify that goods have arrived in the importing country in accordance with the Canadian export permit and the IIC.

- Import Licenses (IL) and End-Use Certificates (EUC) are requested by a Canadian exporter to document that an importer is authorized to receive and use the shipment. The IL or EUC is issued by the importing government and is also submitted to the Export Controls Division of DFAIT.
- End-Use Statements (EUS) may be issued by the importer if their government does not issue the EUCs discussed above. An EUS must identify the end-user, the purpose and use of the goods, match the export permit application, and declare that the imported goods will not be diverted or reexported (DFAIT, 2003).

The U.S. and most of Canada's major trading partners also use the same supporting documentation. To expedite the review process, the DFAIT suggests that exporters attach this documentation to export permit applications. The requirement for the supporting documentation can be waived at the discretion of the Export Controls Division, but this is generally only done for goods in ECL Group 1, Dual Use Goods (DFAIT, 2003). Conditions under which these requirements for end-use documentation can be waived at the discretion of the DFAIT Export Control Division include shipments valued at less than \$10,000 Canadian and shipments to government agencies (DFAIT, 2002).

There are two types of Canadian export permits that can be issued: Individual Export Permits for shipments to one end-user, and General Export Permits (GEP) that allow the export of selected goods to multiple destinations and facilitate the exporting of most goods. A GEP will typically come with instructions for use. However, an agreement with the United States requires an Individual Export Permit for the shipment of materials in Group 3, Nuclear-Nonproliferation List (Jones, 2002). The application is Form EXT-104, Application for Permit to Export Goods, and can be obtained from the DFAIT. Individual export permits are generally valid for one year.

The exporter receives a signed and authorized "Exporter's Copy" when an export application is approved. This copy must be presented to the Canada Customs and Revenue Agency (CCRA) at the port of export. If the permit allows multiple shipments, this copy must be presented with each shipment. The exporter must keep all documents related to each export made under either a GEP or an Individual Export Permit for a period of seven years (DFAIT, 2002).

Most SRSs exported from Canada would not be included on the ECL and would not be destined for countries on the ACL. *Therefore, an export permit and supporting documentation would not be required.* For example, the goods listed in Table 4-1 as typical MDS<sup>™</sup> Nordion<sup>™</sup> exports would not require an export permit unless they were shipped to a country on the ACL. Non-controlled exports of SRSs would require the Canadian Export Declaration Form discussed in the next section and a license from the CNSC. Standard business/commercial paperwork would also include an invoice and the standard shipping paperwork, such as a packing list and a truck bill of lading.

#### 4.1.2.2 Canada Customs and Revenue Agency

The CCRA and the Royal Canadian Mounted Police are responsible for the enforcement of the EIPA, with regulatory authority provided by both the *EIPA* and the Customs Act. CCRA Memorandum D19-10-3 describes the assistance that the CCRA provides the DFAIT in the administration of the EIPA. Customs officials will check the export permit for accuracy and completion, confirm that the permit has been approved and is still in effect, and confirm that the

goods on the permit match those described on all other paperwork (CCRA, 2001). CCRA officials will also review appropriate commercial shipping papers, such as a packing list and bill of lading.

To export goods from Canada, an Export Declaration (Form 13A) must be submitted to the CCRA for all controlled goods and non-controlled goods valued at more than \$2,000. There are 27 required fields on the form, including the following:

- Identification of the Canadian exporter and business number,
- Country of final destination,
- Customs office of exit data and stamp,
- Export permit number (if applicable),
- Number and kind of packages,
- Carrier name,
- Declared value, and
- Item description.

Exporters are required to maintain records of shipments for six years (CCRA 4116). The Export Declaration form can be submitted electronically through the Canadian Automated Export Declaration (CAED) program.

The CCRA inspectors are responsible for examining outbound cargo and documentation and have the authority to detain or confiscate goods. The Strategic Export Controls & Counter-Terrorism Section of the Contraband & Intelligence Services Directorate of the CCRA is responsible for export control intelligence, investigations, and for operation of the classified Signal Intelligence (SIGINT) Registry used by the CCRA (Jones, 2002).

#### 4.1.2.3 Canadian Nuclear Safety Commission

Under Section 26(a) of the *Nuclear Safety and Control Act* (S.C.1997, c.9), a license from the CNSC is required to "possess, transfer, import, export, use, or abandon a nuclear substance, prescribed equipment, or prescribed information." Under Section 2 of the Act, "nuclear substance" includes "a radioactive nuclide." SRSs containing any type of radioactive material would fall under this category and would require a license to export.

The regulations derived from *Nuclear Safety and Control Act* that may be applicable to the export of SRSs from Canada include:

- General Nuclear Safety and Control Regulations,
- Nuclear Non-proliferation Import and Export Control Regulations,
- Nuclear Security Regulations,
- Nuclear Substances and Radiation Device Regulations, and
- Packaging and Transport of Nuclear Substances Regulations.

All licensees are subject to the regulations given in the *General Nuclear Safety and Control Regulations*. To export a SRS, a license application must be submitted to the CNSC that provides the information listed under Section 3 of *General Nuclear Safety and Control Regulations*. Additional requirements are provided for specific materials in the *Nuclear Non-proliferation Import and Export Control Regulations* and in the *Nuclear Substances and Radiation Device Regulations*. Most of the SRSs exported from Canada would be covered under the *Nuclear Substances and Radiation Device Regulations*.

The *Nuclear Non-Proliferation Import and Export Control Regulations* require a license from the CNSC to import or export goods included in Groups 3 and 4 of the ECL. Part A of these regulations addresses the radionuclides of interest included in Group 3, while Part B addresses those in Group 4. This license must be obtained in addition to the export permit issued by the DFAIT.

The license application must include (CG 2000-06-21):

- Applicant's name, address, and telephone number;
- Description of the substance, equipment, or information;
- Name and address of the supplier;
- Country of origin;
- Name, address, and telephone number of each consignee;
- Intended end-use and end-use location;
- The number of any license to possess the substance, equipment, or information; and
- The measures that will be taken to comply with the IAEA Convention on the Physical Protection of Nuclear Material (IAEA, 1980) if the controlled substance is Category I, II, or III nuclear material under the Nuclear Security Regulations (This section would mainly apply to imports.).

Generally this information is already included on the Export Permit Application Form EXT-104 submitted to the DFAIT. The DFAIT will coordinate activities with the CNSC, and a separate application is not required.

The *Nuclear Security Regulations* provide the CNSC requirements for the protection of the plutonium isotopes, U-233, U-235, natural uranium, depleted uranium, thorium, and low-enriched uranium fuels, which are organized into Categories I, II, or III, depending on the quantity of material. In addition to the protection requirements, these regulations also provide the requirements for protection-related information that must be included in an application to possess or transport Category I, II, or III material (CG 2000-06-21).

The *Nuclear Substances and Radiation Device Regulations* provide general requirements for the possession of nuclear substances and license application requirements for the export of radioactive materials. Materials exported from Canada that would fall under these regulations include Co-60 and Cs-137 in SRSs. Record-keeping requirements given in Section 36(1) include documentation of any transfers of material. The radionuclides covered by the license requirements in the *Nuclear Non-proliferation Import and Export Control Regulations*, such as

the plutonium isotopes, U-233 and U-235 are exempt from the import and export license requirements in the *Nuclear Substances and Radiation Device Regulations*.

The *Packaging and Transport of Nuclear Substances Regulations* are based on IAEA guidelines and are applicable to the transport of SRSs within Canada during the export process. Issues addressed in these regulations include the certification of packages, labeling requirements, and requirements for transport documents.

## 4.1.3 How Laws Address Specific Questions

Table 4-2 and the bullets below summarize the Canadian export requirements.

- The DFAIT is responsible for establishing trade controls and issuing export permits for controlled goods. A SRS would be a controlled good if it includes one of the controlled substances listed on the ECL. Potentially applicable ECL groups include Group 3, Nuclear Non-Proliferation List, Group 4, Nuclear-Related Dual Use List, and Group 5, Miscellaneous Goods. The details of the isotopes and materials included in these groups are provided in Section 4.1.2.1 of this report. Supporting documentation required for export permits is listed in Table 4-2.
- The CCRA is responsible for verifying that all export requirements are met for specific shipments, investigating suspicious shipments and exporters, and examining shipments. In addition to verifying that export permits for controlled goods are valid, the CCRA also requires the submission of an Export Declaration Form and standard commercial shipping papers.
- The CNSC is responsible for licensing the import and export of SRSs to and from Canada. SRSs that contain fissile or fissionable radionuclides are licensed according to the requirements given in the *General Nuclear Safety and Control Regulations* and the *Nuclear Non-Proliferation Import and Export Control Regulations*. The more typical SRSs, such as those that contain Co-60 or Cs-137, are licensed according to the requirements given in the General Nuclear Safety and the Nuclear Substances and Radiation Device Regulations.

There are no Canadian regulations that prohibit the return of spent SRSs, or sources that are no longer needed, to the manufacturer. MDS<sup>TM</sup> Nordion<sup>TM</sup>, one of the world's largest manufacturers of SRSs, accepts spent sources returned for disposal for a fee that includes the cost of shipping. A CNSC license is required to import radioactive material, and the return of "spent" sources to the Canadian manufacturer is considered to be importation. Typically, a Canadian manufacturer would have a CNSC license that allows the production, storage, transport, export, and import of specific types of SRSs.

Radioactive sources that contain fissile or fissionable material included on the ECL are also known as "strategic goods" by the CNSC. When these sources are exported from Canada, the recipient (importer) must notify the CNSC upon receipt. These goods are shipped under *Nuclear Cooperation Agreements* that include a requirement for yearly declaration of the materials in possession. In addition, the recipient must get Canada's permission for a "retransfer" of the material. The CNSC reports that most shipments of SRSs categorized as "strategic goods" go to

facilities and countries with proven records for the proper management of the material and the majority of the shipments go to the U.S.<sup>7</sup>

There are currently no notification requirements for SRSs exported from Canada that do not contain materials on the ECL. These exports are essentially conducted business-to-business, with no regulatory oversight from the DFAIT. The CNSC reports that  $MDS^{TM}$  Nordion<sup>TM</sup> verifies that the intended recipient of an export has the appropriate license for possession of the material in their country, but the verification is not a requirement of their CNSC license; it is performed as a good business practice only. As with imports of sources not included on the ECL, possible changes in IAEA guidelines for managing SRS may result in changes in Canada for the tracking of exported sources.<sup>8</sup>

Type of Export	Required by the Department of Foreign Affairs and International Trade, DFAIT <sup>a</sup>	Required by the Canadian Customs and Revenue Agency, CCRA	Required by the Canadian Nuclear Safety Commission, CNSC
Controlled Goods	Export Permit Application (Form EXT-104)	Export Declaration (Form B13A)	Export License
(Goods on the ACL, ECL, or Automatic Firearms Country Control List)	Export permit Supporting documentation (see footnote) International Import Certificates Delivery Verification Certificates End-use certificates and Import Licenses End-use statements	Standard shipping papers (packing list, bill of lading, etc.) (CCRA is responsible for examining shipments. Customs agents will review all DFAIT and CNSC documentation.)	(Applicable regs: General Nuclear Safety and Control Regulations and Nuclear Non-Proliferation Import and Export Control Regulations)
Non-Controlled Goods	No export permit required.	Export Declaration (Form B13A) Standard shipping papers (packing list, bill of lading, etc.)	Export License (Applicable regs: General Nuclear Safety and Control Regulations and Nuclear Substances and Radiation Device Regulations)

#### Table 4-2. Summary of Canadian Export Requirements

a. There are several conditions under which these "end-use" documents can be waived at the discretion of the DFAIT Export Controls Division, including shipments that are valued at less than \$10,000 Canadian (excludes firearms) and exports to government agencies (DFAIT, 2002).

<sup>&</sup>lt;sup>7</sup> Personal communication with Brenda Beriault of the CNSC on 2/24/03.

<sup>&</sup>lt;sup>8</sup> Personal communication with Bob Irwin of the CNSC on 3/18/03.

## 4.1.4 Summary Table

Table 4-3 summarizes the answers to the primary questions of this study for exports of SRSs from Canada.

Approval contingent on infrastructure? <sup>1</sup>	Notify importing country?	Nature of notification?	How are transfers tracked?	Reentry of disused source allowed?
Fissile/Fertile Rad	lionuclides			
Yes – Canada determines which countries can receive these shipments, known as "strategic goods."	Yes – materials are shipped under Nuclear Cooperation Agreements.	Importer must notify CNSC upon receipt. Recipient must also notify the CNSC of further transfers and obtain Canada's permission.	Yearly declaration of the materials in possession is required. Canada must also give permission for "retransfers".	Yes
Non-Fissile/Fertile	e Radionuclides			
Not required by Canadian law, but often done as a good business practice.	Not required by Canadian law, but may be done to accommodate importing country's transportation regulations or voluntarily as a good business practice.	N/A	Not tracked	Yes—considered to be the same as importing.

## 4.2 The Russian Federation

## 4.2.1 Introduction/Nature of Exports

There is little readily available information on the SRS export regulations of the Russian Federation. The effort required to obtain information about Russian export regulations was roughly equal to the efforts required to get information on the other five countries combined. Due to limited project resources and regulatory complexity, this section is based largely on a software translation of Russian regulations acquired by the U.S. State Department through the U.S. Embassy in Moscow, and information from Alardin et al. (1999). Hence, the interpretation of the regulations may not be fully encompassing.

The production and circulation of Russian SRSs is formidable. As of 1999, GOSATOMNADZOR, the Russian nuclear regulator, had licensed the distribution of 844,444

sources throughout Russia (Alardin et al, 1999. p. 79). Currently, about 90% of all new sources produced in Russia are exported. Since 1990, Russian nuclear exports have increase 280%, producing \$38.45 million worth of nuclear goods in 2002. Russia is the only worldwide distributing producer of Cs-137, and they also claim to produce 30% to 60% of the world's Co-60 (Interfax Daily Business Report, 2003).

The main distributor of SRSs in Russia is PO Mayak, which is responsible for production and sales of 52% of all Russian sources (Interfax Daily Business Report, 2003). PO Mayak internally distributed over 23,500 sources of Ir-192, Cs-137, and Co-60 alone with maximum activities of 37, 72, and 320 TBq (1, 2 and 8.7 kCi), respectively. Other isotopes produced by PO Mayak include Sr-90, Am-241, Pu-238/239, Am/Be, Pu/Be, Po-85, Np-237, and Pr-147.

Mayak delivers the new SRSs and receives the spent SRSs through specialized companies, including VO Isotop. Consequently, the manufacturer has no information about the final destination of the sources (Alardin et al, 1999, p. 57). VO Isotop, a main distributor, sent out more than 900 sources from 1992-1997 that totaled more than 10,400 TBq (280 kCi). REVISS, another main distributor, is a joint venture between three companies: Technasbexport (60%), RMT Ventures (30%) and Amersham (10%). REVISS is based in Buckinghamshire, England and has offices Beijing, China, and Illinois, U.S. (http://www.reviss.co.uk/contactus/ contactus.asp).

The second largest producer, GNC FR NIIAR, started in 1972 with Cf-252 production and now specializes in various high-activity sources. Their main production facility is in Dmitrovgrad, Ulyanovsk Region. From 1993-1997, GNC FR NIIAR distributed 2,294 sources of Co-60, Ir-192, Se-75, Cu-244, Cf-252, and Ga-153. NIIAR handles distribution through its own Preparation Division.

Technsabexport, based in Germany, owns part of REVISS and exports for PO Mayak. This company reports exporting about half of all isotopes exported from Russia. The sources produced by all the major producers are used for industry, medicine, agriculture and research (http://www.reviss.co.uk).

Recently, the U.S. government placed a \$32 million dollar contract with Russia to produce up to 40 kg of Pu-238 over a 10-year period for use in RTGs for the U.S. space program. Technsabexport will supply the Pu-238 (Nuclear Waste News, 2003).

## 4.2.2 Regulatory Requirements

There are five major groups controlling the regulation and export of nuclear materials from Russia, which is covered in the following sections. Figure 4-1 illustrates the regulation and export process.

# 4.2.2.1 The Federal Nuclear and Radiation Safety Authority of Russia - GOSATOMNADZOR

GOSATOMNADZOR (GAN) is the highest nuclear regulatory body in the Russian Federation. GAN controls and assures the State's safe production and application of radioactive materials.

GAN is responsible for licensing of all nuclear activities including waste disposal. In order to conduct an activity involving SRSs, one must obtain a license from GOSATOMNADZOR that determines the following (Alardin et al, 1999, 14,15).

- The requirements on radiation safety (e.g. applicable Regulations and Norms).
- The requirements on reporting about the Enterprise activities.
- The requirements on information in case of an accident or other violations of the applicable rules.
- The requirements on physical protection, e.g. the control of access.
- The obligation for the nuclear operators to communicate each year the inventory of the waste accumulated in their faculty.

Governmental Decree No. 865 of 14 July 1997 fixes the conditions and procedures required for obtaining a license.

Although GAN has a high Central Directorate in Moscow, the seven Intermediate Directorates (each covering a number of states) mainly control activities related to SRSs (Alardin et al, 1999, p. 21).

### 4.2.2.2 The State Committee of Sanitary-Epidemic Control – GOSSANEPIDADZOR

The state Committee of Sanitary-Epidemic Control, GOSSANEPINADZOR of Russia, a the subdivision of The Ministry of Health Care (MINZDRAV), is responsible for issuing limited certificates for the right to deliver, distribute, and use ionizing radiation sources. These are known as Sanitary Passports, in accordance with OSP-72/87 and the Passports can be renewed.

Once both GAN and GOSSANEPIDADZOR (Sanitary Passport) licenses are obtained, the shipment leaves the manufacturer with the following documents (Alardin et al, 1999, 42):

- SRSs' Passport (Fig 4-1, rep 3),
- Shipment passport (Fig 4-1, rep 4),
- Waybill (Fig 4-1, rep 5),
- Packing List (Fig 4-1, rep 6), and
- Handling Instructions (Fig 4-1, rep 7).

Also, in accordance with OSP-72/87, the Source Delivery Data (SRS serial number, its characteristics, the delivery date and data concerning the buyer) are registered in the record files of the manufacturing enterprise when the source is shipped (see Figure 4-1, rep.8). If any customer or middleman within Russia receives the shipment for storage or processing before it is exported, they must inform GOSSANEPIDNADZOR and the Ministry of Internal Affairs within 10 days of receiving the shipment. This is done in the form of a receipt notice, which is then filed by the administrative bodies.





One must also obtain a license from both GAN and GOSSANEPINADZOR in order to manufacture, store, utilize, transport, or dispose of sealed sources (Alardin et al., 1999, p. 42).

#### 4.2.2.3 The Ministry for Atomic Energy - MINATOM

According to Alardin et al. (1999) "The Russian Federation's Ministry for Atomic Energy, MINATOM, is responsible for nuclear fuel production, electricity generation at nuclear power plants, spent nuclear fuel reprocessing, collection, conditioning, interim storage and disposal of spent nuclear fuel and of radioactive waste from power plants and reprocessing facilities."

In order to export an SRS, one must submit the following to MINATOM (after obtaining a license from the Ministry of Commerce the following as described in Governmental Decree No. 291 of 10.03.1996):

- The RF Ministry of Commerce export application, which includes information about the country being exported to, the contract and dates of contract, specifications on what is being transported, cost, customs office, and signature of a Ministry of Commerce official (Letter of the RF State Customs Committee dated Jan. 15, 1999, No. 01-15/947) (Fig 4-1, ref. 9).
- A certified copy of a signed or initialed contract for export of the items (Fig 4-1, ref. 10).
- If the exporter is a middleman, certified copies of a commission contract or a contract for purchase or sale with a manufacturer, which stipulate the purchaser's right to sell the subject of the contract in the other countries.
- A certified copy of the permit (license) from the RF Federal Inspectorate for Nuclear and Radiation Safety to the manufacturer and exporter-middleman authorizing work involving the production, storage, transportation, and provision of middleman services in the sale of radioisotope items and radioactive substances (Sanitary Passport, Fig 4-1, ref. 2).

Tritium, Ra-226, Np-237, and radioisotope items based on alpha-emitting isotopes that have a half-life of 10 days or more, but less than 200 years are controlled substance goods, and are regulated by individual decrees.

Once the license is obtained, the RF State Custom's Committee stipulates actual export procedure.

#### 4.2.2.4 The Ministry of Internal Affairs – MVD

The Ministry of Internal Affairs (MVD) is responsible for the commission and inspection of new and existing nuclear facilities in Russia. The Authorization Division is in charge of granting licenses for obtaining sources based on a certificate from the Chief Sanitary Physician (Alardin et al., 1999, p.17). For exportation, they are most involved in transport inside Russia.

Where internal transport is involved, if the SRSs are to be shipped by rail, air, or water, they are not required to submit information on their travel itinerary. However, if they are shipped by road, they need to give the State Road Inspection of MVD data concerning the route, a certificate of approval for the means of the shipments transport, and agreement for the shipment.

# 4.2.2.5 The Ministry of Commerce (formerly The Ministry of Foreign Economic Relations)

The Ministry of Commerce is responsible for regulating import and export within the Russian Federation. According to Regulations Governing the Procedure for export and import into the Russian Federation of Radioactive Substances and Items based on them (Decree No. 1560 of 27.12.1996, and No. 148 of 22.2.2000), the Russian Federal Ministry of Commerce is responsible for controlling export. One must obtain a permit from them to export any good on the goods list of foreign economic activities (GLFEA). All radioisotopes are on this list.

All fissile/fertile radionuclides are controlled with exporting procedures in line with the nonproliferation procedures determined by the IAEA. However, these procedures can be overridden by the DUMA if the importing country has appropriate facilities and Russia receives a certified document from the country they are exporting to as to the appropriate use of the material.

#### 4.2.2.6 RF State Customs Committee

The State Customs Committee is in charge of checking goods imported and exported through the border of Russia. When MINATOM and GAN receive the documentation for licensing export and grant it, they are required to send a copy of the documents to the State Customs Committee (State Customs Committee Order No. 242 May 17, 1997, Table 4.1).

At the customs checkpoint, an initial radiation control check is carried out by means of permanent stationary mounted boundary checkpoints. All those crossing the border are required to pass through these checkpoints. If further inspection is necessary, it is carried out using a high-sensitivity portable detection device. If the source can still not be localized, it is brought to a specialized scanning site inside of Russia and scanned thoroughly there (State Customs Committee Order No. 242 May 17, 1997, 6.2-6.4).

Customs makes certain that all the appropriate documents are there and certified, that the shipping cask is appropriate for the contents (following Gostandart regulations), and that all the requirements for Rules of Transportation are followed. If the item is not in conformation with the specifications of the license, action must be taken within 12 hours.

Nowhere is it mentioned that SRSs shall only be shipped to organizations outside Russia that have provided proof that they are authorized by their regulatory authorities to possess such material.

The SRS passport contains information on the SRS, including surface dose rate, type of nuclide, activity of nuclide and dimensions of the source, and date manufactured, as well as a list of the requirements for storage, utilization, and a manufacturing guarantee (an expiration date for quality of goods) (Alardin et al., 1999, p. 197).

## 4.2.3 How Laws Address Specific Questions

The Russian Ministry of Commerce (Economic Development and Trade) has the right to grant export of fissile/controlled goods (Ministry of Foreign Affairs Press Release No. 0823, June 22 2001). The State Customs Committee is in charge of inspecting the SRS and assuring that all

required licenses and paperwork are valid, as well as investigating suspicious shipments. They also assure that the source and source transport conform to Russian Federal standards.

The Ministry of Commerce is in charge of determining the requirements for and issuing licenses for export of radioactive goods that are not considered weapons grade fissile materials. These sources are licensed according to the GOSSANEPIDADZOR and GAN regulations.

Several articles (e.g., 6, 7, 8, 9, 50 and 540) of Law n\* 2060-1 of 19.12.1991 *On the Environmental Protection* concern the organization and the control of the nuclear activities. In particular, article 50.3 states that "It is prohibited to import radioactive waste and radioactive materials from other countries for storage and disposal, dumping, disposal in outer space." Therefore, a disused source can be returned to Russia for reuse or recycling, but a disused RS cannot be returned as radioactive waste for storage and disposal.

## 4.2.4 Summary Table

Table 4-4 presents a summary of the answers to the primary questions of this study for exports of SRSs from the Russian Federation.

Approval contingent on infrastructure?	Notify importing country?	Nature of notification?	How are transfers tracked?	Reentry disused source allowed?
Fissile/Fertile R	adionuclides			
Yes <sup>a</sup>	No	N/A	Ministry of Commerce tracks export attempts, along with State Customs Committee (also delivery notice to MVD)	No, if classified as "waste" (yes if recycle)
Non-Fissile/Fert	ile Radionuc	lides		
No	No	N/A	Delivery notice sent to MVD, State Customs Committee receives granted license info; including export	No, if classified as "waste" (yes if recycle)

<sup>a</sup> The receiving country must be in line with the non-proliferation procedures determined by the IAEA, but the Duma may override this and ship to an outside state, if they receive official written verification from the receiving government that the appropriate safeguards are in place.

## 4.3 South Africa

## 4.3.1 Introduction/Nature of Exports

Sealed radioactive sources are produced by the Nuclear Technology Products (NTP) division of the South African Nuclear Energy Corporation (NECSA). NECSA is owned by the government of South Africa and was created in 1999, replacing the Atomic Energy Corporation (ACC), when the regulation of nuclear safety was separated from the development and application of nuclear technology (Republic of South Africa Nuclear Energy Bill B 10-99).

The NTP facility is located in Pelindaba, South Africa and produces SRSs using the SAFARI-1 high flux reactor. Sources produced include Ir-192 radiography sources ranging in activity from 1 to 4 TBq (30 to 120 Ci) and Cs-137 sources with a maximum activity of 30 GBq (0.8 Ci), used for level and density control, flow rate measurement, belt weighing, static elimination, column scanning, and moisture measurement. Additional NTP products include radiochemicals and radiopharmaceutical kits containing molybdenum-99/technetium-99m, iodine-131, phosphorous-32 and sulfur-35. The NTP isotope production facilities are ISO 9002 certified (NTP website).

The quantity of SRSs exported annually from South Africa is unknown. However, a NECSA representative reported that only relatively small sources, e.g., less than 185 GBq (5 Ci), have been exported from South Africa.<sup>9</sup>

## 4.3.2 Regulatory Requirements

## 4.3.2.1 National Nuclear Regulator

The National Nuclear Regulator (NNR) of South Africa is responsible for the regulation of nuclear installations, radioactive waste, irradiated nuclear fuel, and the mining and processing of radioactive ores and minerals. The NNR was created in 1999, replacing the Council for Nuclear Safety. The regulatory authority for the NNR is derived from the National Nuclear Regulator Act (Act No 47 of 1999). A Board of Directors appointed by the South African Minister of Minerals and Energy directs the NNR. The NECSA site at Pelindaba is one of the facilities regulated by the NNR. However, the export of sources from the NECSA facilities is regulated by the Department of Health, as discussed below.

## 4.3.2.2 Department of Health

The Radiation Control Directorate of the South African Department of Health regulates the production, transport, disposal, import, export, and possession of SRSs under the *Hazardous Substances Act* (Act No. 15 of 1973). Fabricated radioisotopes are included as Group IV Hazardous Substances in the Act if the activity concentration is greater than 100 Bq/gram. Materials with activities less than 100 Bq/gram can also be regulated as Group IV substances if so designated by the Minister of National Health.

<sup>&</sup>lt;sup>9</sup> Personal communication; M.E. Smith of NECSA, March 6, 2003

The regulations applicable to SRSs exported from South Africa are provided in the *Regulations Relating To Group IV Hazardous Substances*, No. R. 247, February 26, 1993, and provided in the *Government Gazette* (No. 14596), February 26, 1993. To export SRSs from South Africa, the Department of Health issues NECSA an "Authority," which is similar to a license. The NECSA authority is valid for one year and covers multiple sources. The authorities issued to all other exporters are also valid for one year.

To apply for an authority, the *Application for Authority in Terms of Article 3A of the Hazardous Substances Act, 1973 (Act 15 of 1973) To Export, Convey and Cause to Convey Radioactive Nuclides* (Form RN782E) must be completed and submitted to the Director-General of Radiation Control of the Department of Health. Information that must be provided on the application includes:

- Company name,
- Company registration number,
- Company address,
- Identification of the radiation protection officer and description of applicable experience,
- Identification of the acting radiation protection officer and description of applicable experience,
- Details of radiation monitoring equipment,
- Purpose of export,
- Country to which the source will be exported,
- Type of export (permanent or temporary),
- Details on sources to be exported, including type of radionuclides, activities, serial numbers, physical forms, and application of the sources,
- Supplier of radioactive sources to be exported,
- Description of packaging, and
- Transport mode.

Additional Department of Health forms that apply to the management of SRSs include:

- *Particulars of Sealed Radioactive Source* (Form RN608E), used to describe each source, and document leak tests and disposal.
- Report Following The Loss/Theft Of, Or Damage To A Radionuclide Source (Form RN900).
- Application For Authority In Terms of Article 3A Of The Hazardous Substances Act, 1973 (Act 15 of1973) For Disposal (Discarding) of Sealed Radioactive Material (From RN525).

Section 9 of the *Regulations Relating To Group IV Hazardous Substances* provides the requirements for permanent "stock records," which each authority holder must keep concerning the radioactive materials under their control. These records must be updated daily and inspected by the radiation control officer at least once a month. In addition, each authority holder must inventory all sealed sources (at minimum) once a year. This annual inventory must be completed

within 14 days after the end of December and the result sent to the Director-General at the end of January. The report must include a statement from the radiation protection officer noting any problems with the inventory as compared to the applicable authority. Section 26, "Duties of Radiation Protection Officer", also requires an inventory when the radiation protection officer resigns, or when a new officer takes over the duties.

The information provided in the stock records must include:

- Name and activity of each substance,
- The date the substance was acquired or came under the authority holder's control,
- The purpose of the substance,
- Identification of the substance as sealed or unsealed, and if sealed, the serial number,
- Disposal date, and
- Date of specific action taken concerning the substance.

### 4.3.2.3 NECSA Authority and Procedures

NECSA holds Authority No. 0888/0/02/0848, issued by the Radiation Control Directorate of the South African Department of Health. This Authority is valid for one year and allows NECSA to export, import, transport, and dispose of sealed sources containing the following radioisotopes:

- Ir-192,
- Cs-137,
- Co-60,
- Am-241,
- Am/Be,
- Po-210,
- Iron-55,
- Sr-90,
- Ca-109,
- Th-201,
- Ra-226,
- Pu-238,
- Cu-244, and
- Io-125.

Of these sources, only Ir-192 is listed as an "industrial radiography source"; the others are listed as "sealed source." The Authority limits exports to only IAEA Member States.

The Annexure to Authority 0888/0/02/0848, Additional Conditions requires the submittal of a monthly report that includes a description of the radionuclides and activities, the country to

which the radionuclides were exported, and the date of export. This Annexure also states that the "authority is only valid for imports and exports to and from IAEA member states who comply with IAEA and IATA transport regulations."

The procedure that addresses the management of sealed sources controlled by NECSA is *Control of Sealed Radioactive Sources* (AEC, 1999). This document refers to the CNS, which was replaced by the NNR, and to the AEC, which was replaced by NECSA. The discussion of this document (below) will use the acronyms for the current names, NNR and NECSA.

The document *Control of Sealed Radioactive Sources* applies to the tracking and documentation of sealed sources at the NECSA facilities. The NECSA nuclear facility managers (NFM) are responsible for the maintenance of a source register that documents the procurement, safe use, transfer, storage, and disposal of sealed sources. The NFM is required to provide a copy of the register to Risk Management: Safety Support (RM (RS)), each year at the end of March and September. The NFM is also required to notify RM (RS) and the NNR each month of the procurement, transfer, and disposal of sealed sources. The source registry information submitted to the NNR is included in a national registry of radioactive sources in South Africa.

RM (RS) serves a centralized function at NECSA and is responsible for:

- Maintaining a central source register,
- Providing the NNR with a bi-annual status reports containing the information recorded in the facility source registers, and
- Submitting a copy of the central source register to the NNR at the end of each calendar year.

Section 6.3 of the *Control of Sealed Radioactive Sources* requires that the NNR be informed of all sources that are to be exported. Section 7 requires NECSA source registers to include the following information:

- Name of the nuclear facility where the sources are located,
- Name of the person responsible for the source,
- Radionuclides,
- Activity,
- Identification number,
- Date produced,
- Company or facility that produced the source,
- Storage location,
- Date transferred,
- Details of the company the source was transferred to, and
- Disposal date (applicable to Nuclear Liabilities Management, which is the division of NECSA responsible for waste disposal).

The source registry information submitted to the NNR is included in a national registry of radioactive sources in South Africa. In addition, NECSA agents often install process control sources in neighboring countries, such as Botswana, Swaziland, and Namibia, and consequently perform the regular checks of those sources. Because they are involved in the installation and source checks, NECSA also maintains fairly accurate records of NECSA sources in those countries.<sup>10</sup>

The export of radioactive material is also addressed in the NECSA document titled *Off-Site Transport of Radioactive Material or Contaminated Equipment* (NECSA, 2001). Section 4.7 of that document states that

Radioactive material or contaminated equipment shall only be shipped to organizations outside South Africa which have provided proof that they are authorized by their regulatory authorities to possess such material or equipment.

## 4.3.3 How Laws Address Specific Questions

Table 4-5 summarizes the status of export control for radioactive sources manufactured in South Africa. Two government agencies, the National Nuclear Regulator and the Department of Health, are involved with the regulation of sealed source production and export in South Africa. The tracking of SRSs in South Africa is required under the *Hazardous Substances Act, 1973 (Act No. 15 of 1973)* and the *Regulations Relating to Group IV Hazardous Substance.* Source registers that include documentation of exports must be sent to the National Nuclear Regulator and the Department of Health on a routine basis. In terms of assuring that sources are exported only to countries with the infrastructure to safely and securely manage the material, exports may only be made to countries that are IAEA Member States and comply with IAEA and IATA transport regulations.

## 4.3.4 Summary Table

Table 4-5 presents a summary of the answers to the primary questions of this study for exports of SRSs from South Africa.

<sup>&</sup>lt;sup>10</sup> Personal communication; M.E. Smith of NECSA, May 21, 2003.

Approval contingent on infrastructure?	Notify importing country?	Nature of notification?	How are transfers tracked?	Reentry disused source allowed?
Fissile/Fertile Rad	dionuclides			
Yes <sup>a</sup>	No	N/A	Reports to National Nuclear Regulator and Department of Health	Yes – disposal included in cost of source.
Non-Fissile/Fert	ile Radionuc	lides		
Yes <sup>a</sup>	No	N/A	Reports to National Nuclear Regulator and Department of Health	Yes – disposal included in cost of source.
<sup>a</sup> NECSA is authorize proof they are authori	ed to export to or zed by their regi	nly IAEA Member alatory authority to	T States and to organizate possess such materials	tions that have prover

## Table 4-5. Summary of South African Notification and Tracking Requirements

# 5. Importing Countries

This chapter presents a detailed review of the laws governing the import of SRSs into Egypt, the Philippines, and the U.S. Each country is reviewed using a consistent format which covers introduction and nature of imports; the regulatory requirements associated with the import of SRSs; how the laws address specific questions posed in the statement of work; and a table summarizing the key aspects of the import regulations.

## 5.1 Arab Republic of Egypt

## 5.1.1 Introduction/Nature of Imports

In Egypt, approximately 4,200 licenses have been issued for the use of SRSs and approximately 200 SRSs were imported in 2002.<sup>11</sup>

## 5.1.2 Regulatory Requirements

#### 5.1.2.1 Regulatory Requirements to Import Radioactive Sources

The regulation of ionizing radiation is defined in the Decree of the President of the United Arab Republic, Law 59 of 1960, "On the regulation of work with Ionizing Radiation and the Protection against its dangers." The introduction of the law references several existing laws, such as Law 415 of 1954 on the Practice of Medicine in the territory of Egypt; Decree 96 of 1952 on the Practice of Medical Professionals in the territory of Syria; and Decree of the President of the Republic No. 288 of 1957 establishing the Atomic Energy Establishment of Egypt.

#### 5.1.2.2 Regulatory Requirements for Possessing Radioactive Sources

Article 1 of the law states that ionizing radiation may not be used by any person whatsoever unless authorized duly to do so. Article 2 states that no permit shall be authorized for the possession of radioactive material unless conditions for protection are provided in accordance with the provision of the law. No authorization shall be issued unless such use is under the supervision of a person entrusted with the task of ensuring implementation of the conditions for protection. As required by Article 2, the license must be renewed if:

- The SRS is transferred or the specifications are changed,
- The surroundings have been subjected to change that influences the conditions of protection, or
- The quantities are increased or new radioactive material has been added.

<sup>&</sup>lt;sup>11</sup> Personal communication between John Cochran and Dr. Aly El-Garf, Head of the Executive Office for Radiation Protection, Egyptian Ministry of Health and Population, May 29, 2003.

The Ministry of Health shall issue licenses for "closed isotopes" (i.e., SRSs) and for regulating all matters pertaining to the protection from its dangers. The Atomic Energy Establishment (now the Egyptian Atomic Energy Agency (EAEA)) shall regulate work in "open isotopes" and reactors and grant licensees to establish reactors, and shall regulate all matters pertaining to the protection from the dangers from reactors (Article 3).

The Ministry of Health is responsible for setting general policies to regulate work with ionizing radiation and for setting rules for the equivalence of foreign certificates of science connected with the practice of ionizing work (Article 4).

Article 5 states that a technical commission shall be setup under the Ministry of Health for the two territories of the Republic (Syria and Egypt) to:

- Grant licenses for closed isotopes (i.e., SRSs),
- Grant licenses to practice as a health physicist,
- Grant licenses for work as technical assistants in X-rays, closed, and open isotopes, and
- Authorize the use of ionizing radiation by any person other than a physician.

Article 10 requires a registration fee. Articles 11 through 15 define the qualifications of persons who may be authorized to use "medical rays." Article 18 requires the government inspection of licensed facilities. Licensed facilities that do not meet provisions of this law shall be closed (Article 20). Article 21 defines penalties of up to two years of imprisonment for violation of the requirements of this law.

Finally, and importantly, Article 28 states "The Executive Minister of Health shall issue the necessary regulations to implement the provisions of the present Law."

In summary, ionizing radiation from closed sources is regulated by Decree of the President of the United Arab Republic, Law 59 of 1960. Law 59 is old, but defines a framework that includes requirements for safety, licensing, inspections, penalties, and assigns to the Minister of Health the responsibility for developing and enforcing implementing regulations.

#### 5.1.2.3 Ministry of Health Implementing Regulations

The Executive Office for Radiation Protection (EORP), Ministry of Health and Population implementing regulations for the import of SRSs into Egypt are in Arabic. An English translation of these regulations has been offered, but has not been received as of the writing of this report.<sup>12</sup>

The Egyptian authority regulating SRSs is the EORP. Only EORP can grant a license to own and use SRSs. A license is granted by the EORP if the licensee meets applicable requirements, most of which are related to assuring radiological safety.

<sup>&</sup>lt;sup>12</sup> Dr. Ali El-Garf, Director General of Radiology, Executive Office for Radiation Protection (EORP), Egyptian Ministry of Health and Population, verbally described these implementing regulations to John Cochran on May 29, 2003.

A license for possession carries with it the authorization to import SRSs; however, a permit to import must be obtained from EORP. Exemptions are provided for certain items, usually consumer products such as self-luminous timepieces and smoke detectors. In general, these exemptions do not apply to SRSs. A SRS cannot be imported without permission of EORP.

Transfers of SRSs can be made only to someone holding a valid license, or to someone abroad under a valid export license. At a minimum, the transfer must be reported to the EORP. Licensees must keep records showing the receipt, location, use, transfer, export, loss, and disposal of SRSs for which they have licenses. Finally, radioactive waste cannot be imported in to Egypt.

## 5.1.3 How Laws Address Specific Questions

The EORP must grant permission to import a SRS into Egypt. EORP and the licensees must keep records of the transfer of SRSs. EORP keeps a registry of all SRSs in Egypt, as well as records of SRSs imported and exported.

## 5.1.4 Summary Table

Table 5-1 presents a summary of the answers to the primary questions of this study for imports of SRSs to Egypt.

Country	Notification of SRS Import Required?	Nature of Notification?	How are SRS imports tracked?	Can disused SRSs be imported?	
Egypt	Yes	Import permit required by	EORP maintains records of all SRSs	Yes for disused SRS, no for	
		EORP	ın Egypt	radioactive waste	
<sup>a</sup> . Implementing regulations based on verbal description and Egyptian law does not differentiate between SRSs					

Table 5-1 Summary	of Equation	Notification and	Tracking F	2001 iromonts <sup>a</sup>
Table 5-1. Summary	л суурнан	Nouncation and	Tracking r	vequirements

<sup>a</sup>. Implementing regulations based on verbal description and Egyptian law does not differentiate between SRSs containing fissile and non-fissile radionuclides.

# 5.2 Republic of the Philippines

## 5.2.1 Introduction/Nature of Imports

The exact number of radioactive sources imported annually into the Republic of the Philippines is unknown, however, the Philippine Nuclear Research Institute (PNRI) reports that, in 2001, it issued 437 certificates for transport and release for SRSs so that the licensees could retrieve the sealed sources from the Bureau of Customs (PNRI, 2001). Assuming that a single certificate of transport and release could be used for multiple SRSs contained in a single package, it is likely that more than 437 SRSs were imported into the Philippines in 2001. PNRI also reports that, in

2001, it issued 339 licenses for the use of radioactive materials in industrial radiography, industry, medicine, and commercial sales (PNRI, 2001). This represents an increase from 2000, during which the PNRI issued 299 licenses for the use of radioactive materials (PNRI, 2001). Based on these facts, the authors conclude that there are probably several thousand licensees in the Philippines and (on average) at least one source is imported into the Philippines each day.

## 5.2.2 Regulatory Requirements

#### 5.2.2.1 Regulatory Requirements to Import Radioactive Sources

According to the Philippine Bureau of Customs, radioactive materials are categorized as "regulated/restricted commodities," meaning that a permit must be obtained from the PNRI before the materials can be imported. The PNRI, which is the Philippine regulatory authority for regulating radioactive materials publishes its regulations in the Code of PAEC Regulations (CPR), grants the right to import radioactive materials to anyone with a license to own radioactive materials:

<u>CPR Part 2, Section 30 (h):</u> Except as otherwise provided in the license, the licensee shall carry with it the right to import, acquire, receive, own, and possess the radioactive material specified on the license.

Although a licensee has the right to import radioactive material, the licensee is required to notify the PNRI when the imported sealed source is scheduled to arrive at a Philippine Customs port of entry and to submit copies of shipping documents (CPR Part 4, Sections 27 and 43; draft)<sup>13</sup>. Once the PNRI has verified the shipment, the PNRI will issue a certificate that the licensee can use to release the shipment from the customs cargo hold area.

Because licenses for possession carry with them the authorization to import radioactive sealed sources, it is necessary to investigate the regulations authorizing possession of radioactive sealed sources to determine the notification and tracking requirements. The requirements for possessing radioactive sealed sources are discussed in the next section.

#### 5.2.2.1 Regulatory Requirements for Possessing Radioactive Sources

Only the PNRI can grant a license to own and use radioactive sealed sources. Licensing and regulatory requirements are given in CPR Part 0 through CPR Part 16. Those CPRs relevant to licensing the use of sealed sources are shown in Table 5-2.

According to CPR Part 2, Section 3,

"Except for persons exempt as provided in this part, no person shall manufacture, produce, transfer, sell, receive, acquire, own possess, use, import or export radioactive material except as authorized in a license issued pursuant to these rules and regulations;..."

<sup>&</sup>lt;sup>13</sup> CPR Part 4 is in draft form so its requirements are, presumably, not yet legally binding. However, pertinent requirements are given here in anticipation of CPR Part 4 becoming codified in the near future.

Exemptions are provided for those using radioactive material in a PNRI-owned laboratory or under a PNRI contract (Section 6); common and contract carriers, freight forwarders, and

Regulation	Title
CPR Part 2	Licensing of Radioactive Material
CPR Part 4	Regulations for the Safe Transport of Radioactive Materials in the
CDD Dort 11	Philippines (dian)
CPR Palt II	Requirements for Radiographic Operations
CPR Part 12	Licenses for Medical Use of Sealed Radioactive Sources in Teletherapy
CPR Part 13	Licenses for Medical Use of Radiopharmaceuticals
CPR Part 14	Licenses for Medical Use of Sealed Radioactive Sources in Brachytherapy
CPR Part 15	Licenses for Large Irradiators
CPR Part 16	Licenses for the Use of Sealed Sources Contained in Industrial Devices
CPR Part 17	Licenses for the Commercial Sale and Distribution of Radioactive Materials (draft)

Table 5-2. PNRI Regulations for Possessing Sealed Radioactive Sources

warehousemen (Section 7); the use of radioactive material in quantities that do not exceed those given in Appendix A of CPR Part 2 (Section 8); the use of source material in a mixture in which the source material is by weight less than 0.05% of the mixture (Section 9); the use of ores containing source material (Section 10); and certain items, usually consumer products, containing radioactive material, such as self-luminous timepieces, smoke detectors, spark gap irradiators, etc. (Section 11). In general, these exemptions do not apply to radioactive sealed sources, unless the sealed source is used in a PNRI-owned laboratory or under a PNRI contract. Thus, the use of radioactive sealed sources (except in a PNRI-owned laboratory or under a PNRI contract) requires obtaining a license from the PNRI.

A license is granted by the PNRI if the licensee meets applicable requirements, most of which are related to assuring radiological safety. However, there are requirements related to transferring and tracking radioactive sealed sources:

• Distributors of SRSs must submit quarterly reports to the PNRI identifying the name and address of each person to whom the sources were transferred, the kinds and quantities of radioactive sealed sources, the date of the transfer, and the total activity of radioactive material involved (CPR Part 17, Section 53 (a), draft)<sup>14</sup>.

<sup>&</sup>lt;sup>14</sup> CPR Part 17 is in draft form. It is cited here with the expectation that the cited requirements will not change significantly when it is finally codified.

- Transfers of SRSs can be made only to PNRI, to someone exempt from licensing requirements, someone with a valid license, or someone abroad under a valid export license (CPR Part 2, Section 33 (a)).
- It is the responsibility of the transferor to determine that the transferee is qualified to receive the transferred sealed source (CPR Part 2, Section 33 (b)).
- At a minimum, the transfer must be reported to the PNRI (CPR Part 2, Section 33, (c)). Licensees holding licenses for the use of SRSs in teletherapy and brachytherapy, and for the use of sealed sources in industrial devices, have the additional requirement of obtaining permission from the PNRI prior to transferring the sealed source (CPR Part 12, Section 38; CPR Part 14, Section 32; and CPR Part 16, Section 32).
- Licensees must "keep records showing the receipt, location, use, transfer, export, loss and disposal" of SRSs for which they have licenses (CPR Part 2, Section 38).
- Licensees holding licenses for the use of SRSs in industrial radiography, teletherapy, and industrial devices are required to conduct a quarterly inventory of all SRSs in their possession and to keep records of each inventory for as long as five years (CPR Part 11, Section 33; CPR Part 12, Section 36; and CPR Part 16, Section 9).

## 5.2.3 How Laws Address Specific Questions

### 5.2.3.1 Notification Requirements

- The PNRI must be notified when a licensee imports a SRS into the Philippines. The purpose of this notification is to allow the licensee to retrieve the imported source from customs (draft requirement).
- Distributors of SRSs must file quarterly reports with the PNRI notifying the PNRI of sales and transfers made during the reporting period (draft requirement).
- The transfer of a SRS must, at a minimum, be reported to the PNRI.
- Licensees holding licenses for the use of SRSs in teletherapy and brachytherapy, and for the use of sealed sources in industrial devices, must obtain permission from the PNRI prior to transferring the sealed source.

## 5.2.3.2 Tracking of Transfers

- Transfers of sealed sources must be reported to the PNRI.
- The PNRI has a registry of SRSs (PNRI, 2001), but capabilities are not known.
- Transfers of SRSs are tracked by the individual licensees through their own record-keeping systems.

## 5.2.4 Summary Table

Table 5-3 presents a summary of the answers to the primary questions of this study for imports of SRSs to the Republic of the Philippines.

Country	Notification of SRS Import Required?	Nature of Notification?	How are SRS imports tracked?	Can disused SRSs be imported?
<b>Fissile/Fertile</b> H	Radionuclides			
Philippines	Yes CPR Part 4, Sections 27 and 43 (b) (2)	Proof of shipment for release from Customs	PNRI has registry system for SRS. Capabilities unknown.	The law does not explicitly differentiate in use SRSs from disused SRSs.
Non-Fissile/Fer	tile Radionuclides			
Philippines	Yes CPR Part 4, Sections 27 and 43 (b) (2)	Proof of shipment for release from Customs	PNRI has registry system for SRS. Capabilities unknown. <sup>a</sup>	The law does not explicitly differentiate in use SRSs from disused SRSs.

Table 5-3. Summary of Philippine Notification and Tracking Requirements

<sup>a</sup><u>Annual Report 2001</u>, Philippine Nuclear Research Institute, Department of Science and Technology, Quezon City, Republic of Philippines.

## 5.3 United States of America

## 5.3.1 Introduction/Nature of Imports

The number of radioactive sources imported annually into the United States of America is unknown. However, meaningful estimates of the number of radioactive sources imported annually were located and are summarized in this section.

The U.S. NRC estimates that there are about 200,000 (general and specific) licensees in the U.S. and that these licensees have about 2,000,000 devices; each device can typically include one to four radioactive sources (Broaddus, 2002). It is further estimated that 124,000 of these sources are "large curie sources<sup>15</sup>" (Archuleta, et al., 2002, section II.B.).

It is also estimated that there are hundreds of thousands of very small curie SRSs manufactured in the U.S. each year (Archuleta, et al., 2002). Household smoke detectors are examples of devices containing very small SRSs. A very small curie SRS is defined as a SRS containing a kBq to MBq (micro- to a few milliCi) of radioactive material, and possession of these very small curie SRSs is exempt from licensing (i.e., these SRSs are beyond those owned by the 200,000 licensees).

There are statistics on quantities of radioactive elements, isotopes, and compounds imported and exported from the U.S. (see below), however, the information is not detailed enough to determine the number and character of sources imported annually.

<sup>&</sup>lt;sup>15</sup> For this section on the U.S., a "large curie source" is defined to mean a source that would be classified as greaterthan-class-C waste in the NRC's 10 CFR 61.55 system, if the source were declared waste.

The U.S. Census Bureau, Foreign Trade Statistics, publishes summary statistics on U.S. imports of (a) Co-60, and (b) all other radioactive elements, isotopes, and compounds, excluding Co-60. Based on these summary statistics, in 2002 the U.S. imported approximately 3.6 PBq (98 kCi) of Co-60 and 2.3 PBq (62 kCi) of other radioactive elements, excluding uranium and thorium. Approximately 63% of the Co-60 came from the United Kingdom and 36% came from Canada, while 95% of the other radioactive elements came from Canada, 2% came from South Africa, and 2% came from Germany. These statistics do not indicate what form the imported radionuclides took (e.g., how many were SRSs).

The value of the Co-60 imports was \$23 million and the value of the other elements imported was \$83 million. These statistics do not indicate whether this is the value of the imported radionuclides or the value of the radionuclides and their associated application devices (e.g., the value of Cs-137 and Am-241/Be SRSs in a soil density gauge, or the total value of the soil density gauge).

## 5.3.2 Regulatory Requirements

### 5.3.2.1 Regulatory Requirements to Import Radioactive sources

The NRC regulates the import of SRSs into the U.S. by granting either a specific license or a general license to import radioactive material. The NRC's regulatory requirements for import of SRSs are given in 10 CFR 110. A specific license to import is granted only after person has filed an application with the NRC. A general license to import is granted without paperwork and without the filing of an application with the NRC. A specific license is granted for the operation of SRS devices that require special safety measures; it is only granted to a person that has met certain requirements and has filed an application with the NRC. A general license is granted for sRS devices that require minimal radiation safety measures because the SRS device is of a robust design (IAEA, 1999, p. 25). A general license is issued through NRC regulations – the licensee does not file a specific application with the NRC. Inherently safe SRSs devices (e.g., smoke detectors) are issued to persons without licensing.

#### Specific License to Import

The requirements for a specific license to import radioactive material are given in 10 CFR 110.43:

*§110.43 Import licensing criteria.* 

The review of license applications for imports requiring a specific license under this part is governed by the following criteria:

(a) The proposed import is not inimical to the common defense and security.

(b) The proposed import does not constitute an unreasonable risk to the public health and safety.

(c) Any applicable requirements of subpart A of part 51 of this chapter are satisfied.

(d) With respect to the import of radioactive waste, an appropriate facility has agreed to accept the waste for management or disposal.

#### **General License to Import**

The general license to import radioactive material is granted by the NRC in 10 CFR 110.27:

§110.27 General license for imports.

(a) Except as provided in paragraphs (b) and (c) of this section, a general license is issued to any person to import byproduct, source, or special nuclear material if the consignee is authorized to possess the material under:

- (1) A contract with the Department of Energy;
- (2) An exemption from licensing requirements issued by the Commission; or
- (3) A general or specific NRC or Agreement State license issued by the Commission or a State with which the Commission has entered into an agreement under Section 274b. of the Atomic Energy Act.
- (b) The general license in paragraph (a) of this section does not authorize the import of source or special nuclear material in the form of irradiated fuel that exceeds 100 kilograms per shipment.
- (c) Paragraph (a) of this section does not authorize the import under general license of radioactive waste, other than radioactive waste that is being returned to a United States Government or military facility in the United States that is authorized to possess the material.
- (d) A person importing formula quantities of strategic special nuclear material (as defined in §73.2 of this chapter) under this general license shall provide the notifications required by §73.27 and §73.72 of this chapter.

The radionuclides inside SRSs are typically byproduct material (e.g., Cs-137, and Sr-90) but can also be source or special nuclear material. The NRC in 10 CFR 110.2 defines these terms:

Byproduct material means: (1) any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material (as in a reactor); and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from ore (see 10 CFR 20.1003).

Source material means: (1) natural or depleted uranium or thorium other than special nuclear materials; or (2) ores that contain by weight 0.05 percent or more of uranium, thorium or depleted uranium.

Special nuclear material means plutonium, uranium-233, or uranium enriched above 0.711 percent weight in the isotope-235.

Thus, SRSs can be imported under the general import license, provided that the importer is authorized to possess the material inside the sealed source. That is, a person is authorized to import the radioactive source under a general import license if (1) the person is authorized to possess the source and (2) the source is byproduct, source, or special nuclear material in less than formula quantities. If the SRS contains formula quantities of strategic special nuclear material (e.g., more than 2 kg of plutonium), the source may still be imported under a general import license, but the NRC must be notified. Hence, it is necessary to examine the regulations authorizing possession of radioactive sealed sources to determine the notification and tracking

requirements. The regulatory requirements for possessing radioactive sealed sources are discussed in the next section.

#### 5.3.2.2 Regulatory Requirements for Possessing Radioactive Sources

The authorization to possess a sealed source containing byproduct, source, or special nuclear material can take any one of three forms, as outlined in 10 CFR 110.27 (a):

- a contract with the U.S. Department of Energy (DOE),
- an exemption from licensing requirements issued by the NRC, or
- a general or specific NRC or Agreement State license issued by the NRC or a State with which the NRC has entered into an agreement under Section 274b of the Atomic Energy Act.

The three different forms of authorization for possession of sealed sources are discussed below, with an emphasis on those requirements relating to transfer of sealed sources.

#### DOE Requirements for Possession of SRSs

The DOE's requirements for management of SRSs are given in 10 CFR 835. Guidance for implementing these requirements is given in DOE Guide 441.1-13, *Sealed Radioactive Source Accountability and Control Guide* (1999). According to DOE's guide, each site that possesses and uses SRSs must have a radiological control organization (RCO) that must be notified and grant approval before sealed sources are obtained (imported or from a domestic vendor) or transferred off-site. Inventory checks are to be performed at least every six months, and records are to be updated when sealed sources are received or transferred.

#### **Exemption from Licensing Requirements**

The NRC exempts persons from the requirements for a license to possess a SRS if the source (1) is being used under a DOE or NRC contract, (2) is being used by the U.S. Department of Defense and contains special nuclear material, (3) contains byproduct or source material in low concentrations or quantities, (4) contains naturally occurring radioactive material (as discussed below), or (5) is in certain consumer products. These exemptions are specified in 10 CFR 30.11-16, 18-21 for SRSs and devices containing byproduct material, 10 CFR 40.11-14 for SRSs containing source material, and 10 CFR 70.11-14, 17 for SRSs containing special nuclear material; limits for concentration- and quantity-based exemptions are given in 10 CFR 30.70-71. Exempt devices are frequently consumer products, such as automobile lock illuminators, illuminated watch hands and dials, smoke detectors, incandescent gas mantles, and counterweights containing uranium.

Manufacturers and distributors of SRSs for persons exempted from the requirements for a license under 10 CFR 30.11-16 and 18-21 are required to report certain information to the NRC (10 CFR 32.12, 16, 20, 25, and 29). This information includes specifics about the manufactured source or device (e.g., radionuclide, quantity, concentration) but does not include information about the person to whom the source or device was transferred (e.g., the person who purchased a smoke detector).

#### NRC and Agreement State Licenses for Possession of SRSs

Under Section 274b of the Atomic Energy Act, the NRC can transfer to individual states some of its regulatory authority. As such, the NRC has transferred its authority to regulate certain SRSs

to 32 states, known as Agreement States, while the NRC has regulatory authority over SRSs in the remaining 18 states. An Agreement State's program to regulate radioactive materials must be compatible with the NRC's program and must be adequate to protect public health and safety (NRC, 2000). It is beyond the scope of this document to examine 32 different sets of requirements for possessing SRSs. Therefore, only the NRC's requirements for possessing SRSs will be discussed here.

The NRC regulates possession of SRSs based on the type of radioactive material inside the source (byproduct, special nuclear, or source) and issues two types of licenses for possessing sealed sources (general license and specific license). The NRC does not regulate sealed sources containing naturally occurring radionuclides (e.g., Ra-226) or sealed sources containing accelerator-produced radionuclides (e.g., Co-57); regulation of sealed sources containing these radionuclides is left to individual states whether or not they are Agreement States (Frazier, et al., 2000). The NRC's requirements for *possessing* radioactive sealed sources are outlined in 10 CFR 30, 31, 33, 40, and 70. In addition, 10 CFR 32, 34-36, and 39 contain NRC's requirements for issuing licenses for the manufacture, distribution, and/or use of certain types of radioactive sealed sources and devices. Table 5-4 shows each of these regulations and the area to which each applies.

Regulation	Title
10 CFR 30	Rules of general applicability to domestic licensing of byproduct
	material
10 CFR 31	General domestic licenses for byproduct material
10 CFR 32	Specific domestic licenses to manufacture or transfer certain items
	containing byproduct material
10 CFR 33	Specific domestic licenses of broad scope for byproduct material
10 CFR 34	Licenses for industrial radiography and radiation safety requirements
	for industrial radiographic operations
10 CFR 35	Medical use of byproduct material
10 CFR 36	Licenses and radiation safety requirements for irradiators
10 CFR 39	Licenses and radiation safety requirements for well logging
10 CFR 40	Domestic licensing of source material
10 CFR 70	Domestic licensing of special nuclear material

#### Table 5-4. NRC Regulations for Possessing SRSs

As noted in the table, 10 CFR 30 contains rules that are generally applicable to SRSs containing byproduct material; specific rules for various types of byproduct-containing sealed sources are in 10 CFR 31-36 and 39. The requirements for licensing source material are given in 10 CFR 39 and 40, while the requirements for licensing special nuclear material are given in 10 CFR 39 and 70.

The following sections discuss NRC requirements for possessing sealed sources, categorized by whether the license is general or specific.

**General License to Possess** Requirements for a general license to possess radioactive material are given in 10 CFR 31.3, 5, 7, 8, 10, and 11 for sealed sources containing byproduct material, in 10 CFR 40.22 and 25 for sealed sources containing source material, and in 10 CFR 70.19 for sealed sources containing special nuclear material. Items that require only a general license to possess are designed for people who have little or no knowledge and understanding of radiation protection (e.g., self-luminous exit signs, static eliminators, and density gauges). Approximately 90% of all licensees are general licensees (Broaddus, 2002).

If a general licensee transfers a sealed source, the transferor is required to transfer the sealed source only to someone who is authorized to possess the sealed source, and is responsible for ascertaining that the recipient is authorized to possess the sealed source (10 CFR 30.41, 10 CFR 40.51, 10 CFR 70.42). Records of the transfer must be kept for as long as the material is possessed and for three years following transfer or disposal of the material (10 CFR 30.51, 10 CFR 40.61, 10 CFR 70.51). These requirements apply to all general licensees. Some general licensees have additional requirements, which are discussed below.

General licensees for possessing a SRS licensed under 10 CFR 31.5 (which grants a general license for "detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere") have additional requirements. They must report to the NRC transfers of generally licensed sealed sources when the source is exported, sent back to the distributor, sent to an authorized disposal site, or purchased by another general licensee who will use it at the same location (10 CFR 31.5 (c) (8) (i)). If the source is being transferred to another specific licensee (except for the ones listed above) they must obtain written permission from the NRC before transferring the source (10 CFR 31.5 (c) (8) (iii)). They must also report to the NRC any changes in mailing address (10 CFR 31.5 (c) (14)). General licensees licensed under 10 CFR 31.5 (c)(13))<sup>16</sup> and pay a registration fee of \$450 (10 CFR 170.31). The information obtained from 10 CFR 31.5 general licensees is used by the NRC in its General License Tracking System (GLTS) to track these sources.

These additional requirements for 10 CFR 31.5 general licensees have been in effect since February 2001 (NRC, 2000), and have been designated as being compatibility category B (65 FR 79179), meaning that Agreement State requirements need to be essentially identical to the NRC's (62 FR 46524). Agreement States are required to make any changes to their regulations needed to make them compatible with 10 CFR 31.5 by February 2004 (65 FR 79179). The NRC has focused its tracking efforts on sources generally licensed for use that are considered by the NRC to be higher risk (Broaddus, 2002).

U.S. distributors of SRSs generally licensed for possession under 10 CFR 31.5 are important sources of information for the NRC. They are required to make quarterly reports to the NRC of sources and devices transferred to general licensees and received from general licensees during the reporting period (10 CFR 32.52). If the licensee is in an Agreement State, the distributor is

<sup>&</sup>lt;sup>16</sup> Registration is required for sources exceeding: 370 MBq (10 mCi) of Cs-137, 3.7 MBq (0.1 mCi) of Sr-90, 7 MBq (1 mCi) of Co-60, 37 MBq (1 mCi) of Am-241, or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label.

required to make the report to the responsible Agreement State agency (10 CFR 32.52). This information includes the name and address of the licensee receiving or sending the sealed source, as well as identifying information about the source and device. Information received from the distributors by the NRC is entered into the NRC's GLTS, which currently tracks only NRC licensees. Once experience is gained with the GLTS, the NRC will consider establishing a national database (i.e., one that would include information from Agreement States) (65 FR 79185). Non-U.S. distributors are not permitted to distribute directly to U. S. general licensees. They must establish a U. S. distribution facility and obtain a specific license to possess and distribute devices to generally licensed customers. This type of specific licensee must also file quarterly transfer reports to NRC.

Persons who are licensed to manufacture SRSs that are distributed to general licensees under 10 CFR 31.7 (which grants a general license for luminous safety devices for use in aircraft) must file an annual report with the NRC. This report must state the total quantity of radionuclides transferred, give the general license by name, state the kinds and numbers of luminous devices transferred, and specify the type and quantity of radionuclides in each kind of device. The information received from these distributors is also entered into the NRC's GLTS.

General licensees for possessing a sealed source under 10 CFR 31.11 (which grants a general license for the use of byproduct material for certain in vitro clinical or laboratory testing) must file Form NRC – 483 with the NRC and receive a validated copy of that form with a registration number assigned prior to using the byproduct material. Any changes in the registration information must be reported to the NRC within 30 days of the effective date of the change (10 CFR 31.11 (b) (1) and (e)).

**Specific License to Possess** Requirements for a specific license for possessing and using sealed sources containing byproduct material are given in 10 CFR 32-36 and 39, while requirements for a specific license for possessing and using sealed sources containing source or special nuclear material are given in 10 CFR 39 and 40 and 10 CFR 39 and 70, respectively. SRSs that require a specific license to possess are used in industrial radiography, irradiators, well logging, and in gauging devices, for example. Such devices are designed to be used only by those who have been trained in radiation safety. Specific licensees are subject to some of the same requirements that general licensees are subject to: sealed sources may be transferred only to someone authorized to possess the source, the transferor is responsible for ascertaining that the recipient is authorized to possess the sealed source, and records of the transfer or disposal of the material. Specific licensees (other than manufacturers and distributors of exempt products and generally licensed devices) are not required to report transfers to the NRC, but, in most cases, are required to conduct an inventory on a regular basis to account for all sealed sources (10 CFR 34.29 (a), 10 CFR 35.67 (g), 10 CFR 39.67, and 10 CFR 70.51).

#### 5.3.2.2 Detailed Summary Tables

Table 5-5 summarizes of notification requirements for distributors and licensees, and whether or not the source is tracked by the NRC for exempt, generally licensed, and specifically licensed SRSs.

# Table 5-5. Summary Table for U.S. NRC Notification and Tracking Requirements for Exempt, Generally Licensed, and Specifically Licensed SRSs

	SRS exempt from NRC licensing	SRS generally licensed under section other than 10 CFR 31.5	SRS generally licensed under 10 CFR 31.5	SRS generally licensed under 10 CFR 31.5 and contains quantities of <sup>137</sup> Cs, <sup>90</sup> Sr, <sup>60</sup> Co, <sup>241</sup> Am, or any other transuranic radionuclide exceeding specified limits	SRS specifically licensed under 10 CFR 30, 33- 36, 39, 40, or 70
Notification Requirements for Distributor	Notify NRC of product characteristics and quantities distributed but not information about purchasers. (10 CFR 32.16)	For SRS generally licensed under 10 CFR 31.7 only <sup>a</sup> : Annual report to NRC: name of purchaser, kinds and numbers of devices transferred, quantity radionuclides in device. (10 CFR 32.56)	Quarterly reports to NRC (or Agreement State) with name and address of purchaser or returner, along with identifying information about source and device. (10 CFR 32.52)	Quarterly reports to NRC (or Agreement State) with name and address of purchaser or returner, along with identifying information about source and device. (10 CFR 32.52)	None
Notification Requirements for Licensee When Source is Transferred	N/A	None, although licensee must keep records of transfers for three years. (10 CFR 30.51, 10 CFR 40.61, 10 CFR 70.51) <sup>b</sup>	Notify NRC when source is transferred and of change in mailing address. Obtain written permission from NRC prior to transferring to certain specific licensees. (10 CFR 31.5)	Notify NRC when source is transferred and when mailing address changes. Register source annually and pay \$450 fee. Obtain written permission from NRC prior to transferring to certain specific licensee. (10 CFR 31.5)	None, but licensee must keep records of transfer and inventory their sources on a regular basis.
Source Tracked by NRC	No	No	Yes	Yes	No

<sup>a</sup>10 CFR 31.7 issues a general license for the use of tritium or pm-147 contained in luminous safety devices for use in aircraft. <sup>b</sup>General licensees licensed under 10 CFR 31.11 (General license for use of byproduct material for certain in vitro clinical or laboratory testing) must file Form NRC-483 with the NRC, and general licensees licensed under 10 CFR 40.25 (general license for use of certain industrial products or devices containing depleted uranium) must file Form NRC-244 with the NRC before using the material and report any changes in registration information, such as address.

#### 5.3.2.3 Regulatory Requirements Summary

Because U.S. import law allows those authorized to possess a SRS to import that source, examining U.S. import laws means examining U.S. requirements for possessing SRSs. The U.S. licensing system for radioactive materials is complex; applicable notification and tracking requirements are dependent on whether the licensee is a general licensee or a specific licensee, the radionuclides and their quantities in the sealed sources, what the licensee intends to do with the sealed source (e.g., produce it, distribute it, transport it, use it), and whether the licensee is subject to NRC regulations or the regulations of an Agreement State. One consequence of this structure is that users of sealed sources that pose little radiological hazard (e.g., a luminous dial

on a watch) have few requirements, whereas users of sealed sources that pose great radiological hazard (e.g. a large irradiator) have many requirements.

#### 5.3.2.4 Recent NRC Actions Related to Control of Radioactive sources

In response to the September 11, 2001 terrorist attacks, the NRC has and will continue to review and modify policies and laws. John Hickey of the NRC provided the following summary of recent NRC actions related to control of radioactive sources on August 13, 2003.

Following the terrorist attacks on September 11, 2001, the NRC undertook a comprehensive review of its safeguards and security programs, including security enhancements for NRC-licensed facilities and activities. This includes consideration of security of radioactive sources. The NRC and its Agreement States license about 21,000 licensees nationwide.

The NRC has advised all licensees to improve security, including provisions that would improve security against theft of materials that could be used in an RDD. The NRC has required security upgrades at some large materials facilities, and is evaluating what additional security measures should be implemented. The NRC is assessing what sources are of concern, and is implementing improved methods for tracking, monitoring, and disposal.

Security enhancements implemented or under consideration include personnel background checks, verification of authorizations, stricter import/export controls, increased transportation security, increased tracking of sources, improved alarms and barriers at licensed facilities, and improved response plans. The NRC is coordinating its efforts with DHS, DOE, U.S. Department of Transportation, the States, and other cognizant agencies.

Additionally, the NRC is coordinating with other Federal and State agencies to improve readiness for an RDD or similar incident. The NRC Operations Center is staffed 24 hours per day to respond to any radiological incident.

## 5.3.3 How Laws Address Specific Questions

#### 5.3.3.1 Notification Requirements

- Assuming that SRSs can be imported under a general import license, there are no notification requirements for importing SRSs into the U.S., unless the sealed source contains formula quantities of strategic special nuclear material, in which case the NRC must be notified.
- The transfer of a sealed source under DOE possession requirements must be reported to the radiological control organization of the specific DOE installation if the source is transferred off-site.
- The NRC does not require reporting the transfer of an exempt SRS.
- The transfer of a sealed source that is specifically licensed (for possession) or that is generally licensed (for possession) under a section other than 10 CFR 31.5 or 31.7 is not required to be reported to the NRC.

- The owner or user of a generally licensed SRS that is licensed for possession under 10 CFR 31.5 must notify the NRC (1) when the source is transferred by being exported, sent to an authorized distributor, sent to an authorized disposal site, or is purchased by another general licensee who will use the source at the same site, and (2) when the owner or user has an address change.
- The owner or user of a generally licensed SRS that is licensed for possession under 10 CFR 31.5 must obtain written permission from the NRC prior to transferring the source to a specific licensee, except as outlined above (e.g., for disposal or return).
- The owner or user of a sealed radioactive source generally licensed for possession under 10 CFR 31.5 that contains quantities of Cs-137, Sr-90, Co-60, Am-241, or any other transuranic radionuclide exceeding specified limits must register the sealed source with the NRC.
- Distributors subject to NRC regulations that distribute sealed sources generally licensed for possession under 10 CFR 31.5 or 31.7 are required to notify the NRC (or cognizant Agreement State) of general licensees to which their products are transferred.
- The NRC does not regulate sealed sources containing naturally occurring radionuclides (e.g., Ra-226) or sealed sources containing accelerator-produced radionuclides (e.g., Co-57); regulation of sealed sources containing these radionuclides is left to individual states.
- A total of 32 Agreement States are responsible for regulating the possession of radioactive sources within their own borders. It is beyond the scope of this document to examine 32 different sets of requirements for possessing radioactive sources. However, an Agreement State's program for regulating of radioactive materials must be compatible with the NRC's program and adequate to protect public health and safety.

#### 5.3.3.2 Tracking of Transfers

- The NRC does not track the import of radioactive sealed sources, although such imports may be tracked by other federal organizations, such as the U.S. Department of Commerce.
- Transfers of sealed sources licensed under DOE requirements for possession are tracked by the radiological control organization at each DOE site but do not appear to be tracked by a central organization.
- Transfers of exempt SRSs are not tracked.
- Transfers of specifically licensed (for possession) sealed sources and of sealed sources generally licensed (for possession) under a section other than 10 CFR 31.5 are tracked by the individual licensees but are not tracked by the NRC. An exception: initial transfers to 31.7 licensees and first receipt by 40.25 licensees are tracked.
- The registration and transfer information obtained from persons possessing certain radioactive sealed sources under the 10 CFR 31.5 and 31.7 general license is being stored in the GLTS, a system that can track sources from cradle to grave (Broaddus, 2002). This tracking system is for NRC-regulated states only; it does not include tracking information from Agreement States and the DOE.
#### 5.3.3.3 Other Observations

Except as noted above, if someone is licensed to possess a radioactive source, they are licensed to import a radioactive source, and there is no background check on persons applying for a license to possess.

#### 5.3.4 Summary Table

Table 5-6 presents a summary of the answers to the primary questions of this study for imports of SRSs to the United States.

Table 5-6. Summary of U.S. Notification and Tracking Requirements						
Country	Notification of SRS Import Required?	Nature of Notification?	How are SRS imports tracked?	Can disused SRSs be imported?		
	Fissile/Fertile Radionuclide	es <sup>a</sup>				
United States	No <sup>b</sup> 10 CFR 110.9a, 27(a)	N/A	N/A	Yes 10 CFR 110.27(c), 2 <sup>c</sup>		
	Non-Fissile/Fertile Radion	ıclides <sup>d</sup>				
United States	No <sup>e</sup> 10 CFR 110.9a, 27(a)	N/A	N/A	Yes 10 CFR 110.27(c), 2 <sup>c</sup>		

<sup>a</sup>Defined as "special nuclear material" in the U.S.

<sup>b</sup>Must report to NRC if importing formula quantities of strategic special nuclear material as defined in 10 CFR 73.2. For example, 2 kg or more of Pu<sup>238</sup> is a formula quantity of strategic special nuclear material.

<sup>c</sup>Definition of radioactive waste specifically does not include SRSs being returned to manufacturer.

<sup>d</sup>"By-product material" and "source material" as defined in the U.S.

<sup>e</sup>After importing, registration is required for sources exceeding: 370 MBq (10 mCi) of Cs-137, 3.7 MBq (0.1 mCi) of Sr-90, 7 MBq (1 mCi) of Co-60, 37 MBq (1 mCi) of Am-241, or any other transuranic.

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## 6. Lapses in Import / Export Control

There are a number of reasons for inadvertent lapses in the control of SRSs at a facility: the curator forgets that he/she is responsible for the device containing the SRS; or the curator responsible for the SRS leaves his/her position and is not replaced; or the replacement is not told of the responsibility for the SRS; or the company goes bankrupt (Broaddus, 2002). To determine if there have been inadvertent or advertent lapses in control of SRSs during import or export, the authors consulted the IAEA's International Nuclear Information System (INIS) database of information sources. The INIS database contains over 2,000,000 references related to nuclear science and technology. Access to the INIS database is available through http://www.iaea.org/inis/inis.htm. The INIS database was searched for word combinations such as: radioactive and transportation, and radioactive and accident.

Through the INIS database, the authors did not locate any instances of lapses in control during import or export. However, examples of illegal trafficking in SRSs and examples of accidents indirectly related to the import or export of SRS were identified. The examples of illegal trafficking are summarized first, followed by information on an accident indirectly related to a lapse in import/export control.

Of the millions of annual shipments of radioactive materials, theft and smuggling for malevolent purposes have historically been rare. The IAEA database on illegal trafficking lists 263 confirmed instances of illegal transfers since 1993. Approximately 45% of these cases involved SRSs containing Cs-137, Co-60, Am-241, and Sr-90 (IAEA, 1999, p. 7). A summary of 17 of the illegal trafficking cases is presented in Appendix IV of GAO (2003). The IAEA (2002a) notes that not all of these incidents resulted from deliberate attempts to steal SRSs, and that the majority of the detected incidents involved opportunists or unsophisticated criminals motivated by the hope of profit. Even so, it is believed that a significant number of these cases involve persons who expected to find buyers that could or would deliberately use the stolen radioactive materials to cause or threaten harm (IAEA, 2002a).

In an example of an instance indirectly related to a lapse in import/export control, a Co-60 teletherapy unit was purchased from a hospital in the U.S. by a hospital in Juarez, Mexico in 1977. Mexican authorities were not informed of the import. The Juarez hospital put the teletherapy head in a commercial storage facility without clearly marking the radioactive contents. After a change of personnel at the Juarez hospital, the teletherapy head was sold as scrap metal in 1983. During transport, the SRS was ruptured and some small source pellets scattered along the road. The source was smelted in a metal recycling steel plant. Recycled metal rebar and furniture was distributed in the Juarez, Mexico/El Paso, Texas border region, and only by chance was the contamination discovered by a U.S. national laboratory in northern New Mexico.

There were no deaths, but 75 people received high doses of radiation. In total, 814 houses with activity in the steel reinforcing bars had to be demolished, several foundries required extensive

decontamination, and the cleanup generated 16,000 m<sup>3</sup> of radioactive waste and 4,500 tons of radioactive metal.<sup>17</sup> The cost of the cleanup was estimated at \$34 M (GAO, 2003).

As this study goes to press, the following information was presented by a Texas Bureau of Radiation Control (BRC) Division Director at a technical session of the July, 2003 annual meeting of the Health Physics Society in San Diego California. No other details are available at this time and we present the information verbatim.

On May 6, 2003, the BRC was contacted by the Argentine nuclear regulatory authority. The Argentine authority was seeking to verify whether a Texas entity that ordered radioactive material from Argentina was authorized to receive it. The Argentine authority located the BRC through a search of the internet finding BRC's web site.

The Texas entity, D & M Biomedical, located in McAllen, TX, furnished the Argentines as evidence of authorization a copy of a registration certificate issued to a dentist in Austin, TX. D & M Biomedical installs medical and dental equipment and the dentist was a customer of theirs. The registration certificate had been modified; the listed address was found to be a vacant lot in McAllen. The radioactive material that was ordered was a teletherapy quantity of Co-60 and was destined for Mexico. The TX "licensee" would place the Co-60 into service there. The BRC informed the NRC. The matter is under investigation by the FBI.

The instances of illegal trafficking in SRSs, the Juarez accident, the unsubstantiated Argentine/Texas incident, and the scenarios described in Appendix A provide clear evidence that lapse in import/export control could easily result in a very significant safety or security incident.

<sup>&</sup>lt;sup>17</sup> Interpreted by Brian Dodd of the IAEA from Comision Nacional De Seguridad Nuclear Y Salvaguardias, 1984.

# 7. Summary and Recommendations

### 7.1 Summary of Information Exporting Countries

A detailed review of the laws governing the export of SRSs from Canada, Russia, and South Africa was presented in Sections 4.1 though 4.3. These three countries are among the eight countries that produce the majority of radionuclides used in SRSs distributed worldwide. These three countries cover a broad cross-section of continents, histories, and outputs. Table 7-1 presents a summary of findings relative to the specific questions posed in the scope of work.

Canada is reported to produce 85% of the world's Co-60 and over one-half of the world's medical sterilizers and Co-60 therapy machines. Canada's regulatory system is readily available in English on the worldwide web. They have a significant legal infrastructure involving a number of regulations and regulators governing the export of SRSs. These regulations and regulators address such issues as customs, dual use, taxation, United Nations embargos, safety, and nuclear non-proliferation. Canada verifies the license of an out of country recipient before exporting to countries on the ACL, or before exporting items on the ECL.

An export permit must be obtained for the export of any goods on the ECL. SRSs containing radionuclides that may be fissile or fertile (e.g., Pu-239) are on the ECL and Canada "verifies" before exporting SRSs that contain fertile or fissile radionuclides. For the purposes of this report "verifies" means that Canada notifies the receiving country of the export and Canada verifies that the recipient in the receiving country has a permit to posses such materials. However, most SRSs containing fissile radionuclides are not Category 1 or 2 SRSs<sup>18</sup>.

Non-fissile radioactive materials in SRSs are not on the ECL and Canada does not, as a country, verify before exporting non-fissile Category 1 and 2 SRSs. For example, the goods listed in Table 4-1 as typical MDS<sup>™</sup> Nordion<sup>™</sup> exports would not require an export permit unless they were shipped to a country on the ACL. Canada does allow disused SRSs to be imported. Canadian companies may verify before exporting, but this is done as a prudent business practice, not because Canada legally requires such a review.

Russia's regulatory system is not readily available in English or on the worldwide web, and the effort required to get information about Russian export regulations was roughly equal to the efforts required to get information on the other five countries combined. Due to this difficulty and limited project resources, the interpretation of the regulations may not be fully encompassing.

The production and circulation of Russian SRSs is formidable. As of 1999, GAN, the Russian nuclear regulator, had licensed the distribution of 844,444 sources throughout Russia. Currently, about 90% of all SRSs produced in Russia are exported. Since 1990, Russian nuclear exports have increase 280%, producing \$38.45 million worth of nuclear goods in 2002.

<sup>&</sup>lt;sup>18</sup> Section 3.2 contains an important note on the IAEA Categorization system and alpha-emitting radionuclides.

Country	Approval contingent on infrastructure?	Notify importing country?	Nature of notification?	How are transfers tracked?	Reentry disused source allowed?
Fissile/Fertile Ra	adionuclides				
Canada	Yes	Yes	See Table 4.3	See Table 4.3	Yes
Russia	Yes	No	N/A	Ministry of Commerce and State Customs Committee	No if radioactive waste, yes if recycle
South Africa	Yes	No	N/A	See Table 4.5	Yes –disposal included in cost of source.
Non-Fissile/Fert	ile Radionuclides				
Canada	No	No	N/A	Not tracked	Yes, considered to be the same as importing.
Russia	No	No	N/A	Notice to MVD, State Customs Committee	No if radioactive waste, yes if recycle
South Africa	Yes	No	N/A	See Table 4.5	Yes – disposal included in cost of source.

Table 7-1. Summar	y of Countries	Regulations	Governing	Export of SRS
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VO Isotop, REVISS, NIIAR, and Technsabexport are all distributors of SRSs produced in Russia. REVISS is a joint venture between three companies; Technasbexport, RMT Ventures, and Amersham. NIIAR takes care of distribution through its own Preparation Division, and Technsabexport, based in Germany, owns part of REVISS and exports for PO Mayak.

A significant number of entities are involved in the regulation and export of nuclear materials from Russia, as depicted in Figure 4-1. The Federal Nuclear and Radiation Safety Authority of Russia – GAN– is the highest nuclear regulatory body in the Russian Federation. GAN is responsible for assuring the State's safe production and application of radioactive material, as well as waste disposal. They license all nuclear activities. Although GAN has a high Central Directorate in Moscow, the seven Intermediate Directorates (each covering a number of states) mainly control activities related to SRSs.

The State Committee of Sanitary-Epidemic Control – GOSSANEPIDADZOR, a subdivision of The Ministry of Health, is responsible for issuing limited certificates for the right to deliver, distribute, and use ionizing radiation sources. The Russian Federation's Ministry for Atomic Energy, MINATOM, is responsible for nuclear fuel production, electricity generation at nuclear power plants, production of SRSs, and other related activities.

Within the Russian Federation, the Ministry of Commerce is responsible for regulating import and export. A permit must be obtained from the Ministry of Commerce to export any goods on the goods list of foreign economic activities, and all radioisotopes are on this list.

All fissile/fertile radionuclides are controlled with exporting procedures in line with the nonproliferation procedures determined by the IAEA, Russia applies special controls to exporting SRSs that contain fertile or fissile materials. However, most SRSs containing fissile radionuclides are not classified as Category 1 or 2 SRSs. For non-fissile radionuclides, it does not appear that a Russian permit to export SRSs is contingent on the infrastructure of the receiving country.

Although the output is small compared to Canada and Russia, the Nuclear Technology Products division of the South African Nuclear Energy Corporation (NECSA) produces SRSs using the SAFARI-1 high flux reactor. Sources produced include Ir-192, Cs-137 and radiochemicals and radiopharmaceutical kits containing Mo-99/Tc-99m, iodine-131, phosphorous-32 and sulfur-35. A NECSA representative reported that only relatively small sources, e.g., less than 185 GBq (5 Ci), have been exported from South Africa.

The South African regulatory system is refreshingly straightforward. The National Nuclear Regulator of South Africa is responsible for the regulation of nuclear installations. However, the export of sources from the NECSA facilities is regulated by the Department of Health. To export SRSs from South Africa, the Department of Health issues NECSA an authority, which is similar to a license. In terms of assuring that sources are exported only to countries with the infrastructure to safely and securely manage the material, exports may only be made to countries that are IAEA Members and comply with IAEA and IATA transport regulations. Additionally, the authority requires that "Radioactive material or contaminated equipment shall only be shipped to organizations outside South Africa which have provided proof that they are authorized by their regulatory authorities to possess such material or equipment."

In summary, the countries of Canada and Russia are major exporters and are exporting Category 1 and 2 SRSs without first determining if the recipient is authorized by the receiving country to own and use the SRSs. Canada and Russia verify before exporting SRSs that contains fissile or fertile materials, even though SRSs containing fissile or fertile radionuclides are rarely Category 1 or 2 SRSs. The export of fissile/fertile materials has long been recognized as a security (nuclear non-proliferation) hazard, and such exports are controlled. The authors speculate that Category 1 and 2 SRSs have not been recognized as a security hazard and there are fewer controls on the export of Category 1 and 2 SRSs.

South Africa only exports to organizations outside South Africa that have provided proof that they are authorized by their regulatory authorities to possess such material. The authors speculate that because South Africa sells SRSs to many developing African countries, they have instituted these precautionary measures for safety reasons.

### 7.2 Summary of Information Importing Countries

A detailed review of the laws governing the import of SRSs into Egypt, the Philippines, and the U.S. was presented in Sections 5.1 though 5.3. These three countries cover a broad cross-section of continents and economies. Table 7-2 presents a summary of the findings relative to the specific questions posed in the scope of work.

			II ODO		
Country	Notification of SRS	Nature of Notification?	How are SKS	Can disused SRSs be imported?	
<b>E</b> <sup>•</sup> • <b>1</b>	De d'essend des	Notification:	imports trackeu:	be importeu:	
Fissile/Fertile Radionuclides					
Egypt	Yes	Application to EORP	By EORP	Yes for disused SRSs, no for radioactive waste	
Philippines	Yes	Proof of shipment for release from Customs	PNRI has registry system for SRS. Capabilities unknown.	The law does not seem differentiate SRSs from disused SRSs	
United States	No <sup>a</sup>	N/A	N/A	Yes	
Non-Fissile/Fertile Radionuclides					
Egypt	Yes	Application to EORP	By EORP	Yes for disused SRSs, no for radioactive waste	
Philippines	Yes	Proof of shipment for release from Customs	PNRI has registry system for SRS. Capabilities unknown.	The law does not seem differentiate SRSs from disused SRSs	
United States	No	N/A	N/A	Yes	

Table 7-2, Summary	v of Countries	Regulations	Governing	Import of SRS
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<sup>a</sup>Must report to NRC if importing formula quantities of strategic special nuclear material as defined in 10 CFR 73.2. For example, 2 kg or more of plutonium is a formula quantity of strategic special nuclear material.

Approximately 200 SRSs were imported into Egypt in 2002. The regulation of ionizing radiation is set in the Decree of the President of the United Arab Republic, Law 59 of 1960. The law states that ionizing radiation may not be used by any person unless authorized by license. The EORP, Ministry of Health and Population shall issue licenses for "closed isotopes" (i.e., SRSs) and for regulating all matters pertaining to the protection from its dangers. Egyptian law does not differentiate between SRSs containing fissile and non-fissile radionuclides. Only EORP can grant a license to own and use SRSs. A license is granted by the EORP if the licensee meets applicable requirements, most of which are related to assuring radiological safety. A license for possession carries with it the authorization to import SRSs, however, a permit to import must be

obtained from EORP. EORP keeps a registry of all SRSs in Egypt, as well as records of SRSs imported and exported.

The Philippine Nuclear Research Institute (PNRI) reports that, in 2001, it issued 437 certificates for the import of SRSs. A permit must be obtained from the PNRI before the materials can be imported. The PNRI grants the right to import radioactive materials to anyone with a license to own radioactive materials. Although a licensee has the right to import radioactive material, the licensee is required to get a certificate from the PNRI to release the SRS from the customs cargo hold area. The PNRI has a registry of SRSs, and the individual licensees track SRSs transfers through their own record-keeping systems.

The U.S. regulatory system governing SRSs is complex. As a simplification, regulation of SRSs containing naturally occurring radioactive materials is delegated to each of the 50 states. Regulation of SRSs used in "atomic energy defense activities" is delegated to the DOE. The NRC regulates the remaining SRSs. The NRC exempts from regulation those items owned by the U.S. Department of Defense that contain special nuclear materials. As allowed by Section 274b of the Atomic Energy Act, the NRC has transferred its authority to regulate certain SRSs to 32 states, known as Agreement States, while the NRC has regulatory authority over SRSs in the remaining 18 states. Independent of all other factors, such a complex system hinders the comprehensive regulation and tracking of the import of SRSs.

The exact number of SRSs imported annually into the U.S. is unknown. Based on summary statistics maintained by the U.S. Census Bureau, in 2002 the U.S. imported approximately 3.6 PBq (98 kCi) of Co-60<sup>19</sup> and 2.3 PBq (62 kCi) of other radioactive elements, excluding uranium and thorium.

The NRC regulates SRSs by granting either a specific license or a general license. A specific license is granted to a person only after that person has filed an application with the NRC. General licenses are for SRS devices that require minimal radiation safety measures because the specific SRS devices are of robust designs. A general license is issued through NRC regulations and the licensee does not file a specific application with the NRC. Inherently safe SRSs devices (e.g., smoke detectors) are exempt from licensing. The NRC estimates that there are about 200,000 (general and specific) licensees in the U.S. and that these licensees have about 2,000,000 devices; each device can typically have anywhere from one to four radioactive sources. The NRC and its Agreement States license about 21,000 specific licensees nationwide.

A person is authorized to import the radioactive source under a general import license if (1) the person is authorized to possess the source and (2) the source is byproduct, source, or special nuclear material in less than formula quantities. A license for possession carries with it the authorization to import. If the SRS contains formula quantities of strategic special nuclear material (i.e., fissile material), the source may still be imported under a general import license, but the NRC must be notified. Assuming that SRSs can be imported under a general import license, there are no notification requirements for importing SRSs into the U.S., unless the sealed source contains formula quantities of strategic special nuclear material (e.g., more than 2 kg of

<sup>&</sup>lt;sup>19</sup> This number seems low; the authors are aware of a U.S. facility that received 37 PBq (1 MCi) of Co-60 in a single shipment.

plutonium), in which case the NRC must be notified. Registration (but not prior permission to import) is required for sources exceeding: 370 MBq (10 mCi) of Cs-137, 3.7 MBq (0.1 mCi) of Sr-90, 7 MBq (1 mCi) of Co-60, 37 MBq (1 mCi) of Am-241, or any other transuranic.

SRSs that require a specific license to possess are used in industrial radiography, irradiators, well logging, and gauging devices, for example. Specific licensees are not required to report imports to the NRC, but, in most cases, licensees are required to conduct a check of the inventory on a regular basis to account for all sealed sources.

In summary, Egypt and the Philippines each import several hundred SRSs annually. The number of SRSs imported into the U.S. is unknown, but probably significant. In all three countries, a license to possess a type of SRS carries with it the right to import that type of SRS. Egypt and the Philippines also require government authorization to import. Category 1 and 2 SRSs can be imported into the U.S. without government permission. Special permission to import SRSs into the U.S. is only required for formula quantities of strategic special nuclear materials.

In the U.S., the import of fissile/fertile materials has long been recognized as a security (nuclear non-proliferation) hazard, and such imports are controlled. The authors speculate that Category 1 and 2 SRSs have not been recognized as a security hazard in the U.S. and there are fewer controls on the import of Category 1 and 2 SRSs.

### 7.3 Key Findings and Recommendations

The key findings of this study are:

- Millions of SRSs have been manufactured and disseminated and SRSs are used worldwide in medicine, manufacturing, construction, oil exploration, consumer goods, research, space exploration, and agriculture.
- Through analysis of past accidents and numerical simulations, security experts are now very concerned that Category 1 and 2 SRSs could be used in a RDD to terrorize and disrupt society.
- There are unwanted SRSs that contain long-lived radionuclides in developing countries least able to mange very long-lived radioactive wastes. For these developing countries, one solution is to transfer the disused SRSs to a developed country with the infrastructure and experienced personnel to properly manage these long-lived radioactive wastes.
- Accidents directly resulting from lapses in import or export control were not identified; however, analogues and scenarios make it clear that SRSs being transferred across international borders are susceptible to unauthorized access through theft or acquisition by false pretenses.
- There is a significant worldwide trade in Category 1 and 2 SRSs.
- During transfer, SRSs are particularly vulnerable to theft, since the sources are in a mobile configuration, the transportation routes are known or can be anticipated, commercial carriers may be responsible for shipping, and shipments may not be adequately guarded.

- Canada and Russia export Category 1 and 2 SRSs without requiring proof that the recipient is authorized by their regulatory authorities to possess such material.
- Category 1 and 2 SRSs can be imported into the U.S. without prior permission. A license to possess a type of SRS carries with it the right to import that type of SRS.

Based on these key findings, this study recommends the implementation of better controls over the intercountry transfer of Category 1 and 2 SRSs.

- 1. Exporting countries should only authorize the export of Category 1 and 2 SRSs if the exporting country is satisfied that the recipient is legitimate.
- 2. Exporting countries should maintain a SRS tracking system.
- 3. Exporting countries should allow reentry of disused SRSs for their return to the manufacturer.
- 4. Importing countries that use Category 1 and 2 SRSs must dedicate the resources necessary to manage the SRSs in a manner consistent with internationally recognized standards.

These recommendations are entirely consistent with the IAEA's guidelines for the import and export of radioactive sources contained in the revised *Code of Conduct on the Safety and Security of Radioactive Sources* that was endorsed by the 136 Member States of the IAEA in September 2003. The authors believe that implementation of these recommendations will greatly reduce the probability of diversion and theft of SRSs for malicious purposes. Finally, actions by individual countries are important, but without adoption by all countries, terrorists and criminals will exploit the weakest link in the SRS life cycle

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#### Distribution:

- 10 Andrew Sowder
  Office of Senior Coordinator For Nuclear Safety
  U.S. Department of State
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- John Solmanson Work For Others NNSA SC PO Box 5400 Albuquerque NM 87105
- Karen Henderson Office of International Programs Mail Stop O-4-E-21 Nuclear Regulatory Commission Washington DC 20555

- Brian Dodd or John Wheatley Div. Radiation and Waste Safety Dept. of Nuclear Safety IAEA Wagramer Strasses 5 P.O. Box 100 A-1400 Vienna, Austria
- Victor Levin NAHU Division of Human Health Dept. of Nuclear Sciences IAEA Wagramer Strasses 5 P.O. Box 100 A-1400 Vienna, Austria
- Stan Vatnitsky DMRP
   Division of Human Health
   Dept. of Nuclear Sciences
   IAEA
   Wagramer Strasses 5
   P.O. Box 100
   A-1400 Vienna, Austria
- Mohamed Al-Mughrabi Div. Nuclear Fuel Cycle & Waste Tech Dept. of Nuclear Energy IAEA Wagramer Strasses 5 P.O. Box 100 A-1400 Vienna, Austria
- Ramesh Dayal, Div. Nuclear Fuel Cycle & Waste Tech Dept. of Nuclear Energy IAEA Wagramer Strasses 5 P.O. Box 100 A-1400 Vienna, Austria

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