United States International Trade Commission

Stable and Radioactive Isotopes

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PREFACE

The United States International Trade Commission has initiated its current Industry and Trade Summary series of reports to provide information on the rapidly evolving trade and competitive situation of the thousands of products imported into and exported from the United States. Over the past 20 years, U.S. international trade in goods and services has risen by almost 400 percent. International supply chains have become more global and competition has increased. Each Industry and Trade Summary addresses a different commodity/industry and contains information on trends in consumption, production, and trade, and an analysis of factors affecting industry trends and competitiveness in domestic and foreign markets. This report on stable and radioactive isotopes primarily covers the period 2003 through 2007.

Papers in this series reflect on-going research by USITC international trade analysts. The work does not represent the views of the United States International Trade Commission or any of its individual Commissioners. This paper should be cited as the work of the author only, and not as an official Commission document.

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ABSTRACT

This report addresses trade and industry conditions for stable and radioactive isotopes for the period 2003 through 2007.

- Isotopes, stable and radioactive, play key roles in healthcare, industrial processes, and national security, yet the U.S. industry is highly import dependent for the raw isotopes used in the formulation of end products. Stable and radioactive isotopes (radioisotopes) are utilized in a variety of medical and industrial applications ranging from diagnostic and therapeutic products to screening devices used to detect explosives and drugs. The estimated value of U.S. isotope shipments in 2007 was about $3 billion.

- Nuclear medicine is the largest market for isotopes (by value). The U.S. nuclear medicine industry is valued at about $1.7 billion, buoyed by an increasing number of nuclear medical procedures. The second largest market is for industrial isotopes. The production of industrial isotopes, however, has reportedly been declining in recent years, largely because of health and security concerns involving radioactive materials.

- There is no domestic source for most of the raw radioisotopes used in medical procedures. During the past 40 years, the U.S. Department of Energy (DOE) and, to some extent, private industry, have ceased producing certain isotopes. Reasons vary, but include relatively high U.S. production costs; the availability of adequate supplies of isotopes from other countries, especially Canada, the European Union (EU) and Russia; the policy of the DOE not to compete with the private sector; and restrictions imposed on the private industry in operating nuclear reactors.

- The United States has become dependent on foreign sources for many important basic isotopes, including molybdenum-99/technetium-99m, which accounts for over 70 percent of nuclear medical procedures. The United States currently imports close to 90 percent by volume of the raw isotopes consumed domestically, including its entire supply of molybdenum-99, primarily from Canada and the EU. Concern about the availability of molybdenum-99 has taken on new urgency following the decision of the Atomic Energy of Canada Ltd. to immediately discontinue development work on two reactors that were to replace Canada's aging production facility for molybdenum-99 in Chalk River, Ontario.

- Isotopes are used to irradiate food and medical supplies to reduce bacterial levels and minimize spoilage. In 2008, the U.S. Food and Drug Administration approved for the first time the use of irradiation on produce to kill disease-causing *E. Coli* and salmonella, partly in response to nation-wide outbreaks of the two pathogens. Irradiated food use may grow rapidly if customer concerns about irradiation can be eased.

- The U.S. isotope industry has been one of the most regulated in the United States. To meet regulatory and other challenges, which were exacerbated following the events of September 11, 2001, the private isotope industry has adopted a number of measures to reduce costs and to increase efficiency. The industry has also undergone considerable consolidation, largely through mergers and acquisitions, in part with an eye on increasing the level of vertical and horizontal integration of the major producers.

INTRODUCTION

Isotopes play key roles in healthcare, industrial processes, and national security. Stable and radioactive isotopes (also called radioisotopes; see box 1) are utilized in a variety of medical and industrial applications ranging from diagnostic and therapeutic products to screening devices used to detect explosives and drugs. The estimated value of U.S. isotope shipments in 2007 was about $3 billion. The industry has grown rapidly largely as a result of advances in nuclear medicine, the primary market for these products.

Box 1. Definitions of isotopes and radioisotopes

Matter is composed of atoms whose nuclei contain protons and neutrons. The number of protons in the nuclei determines whether the atom is hydrogen, carbon, uranium, oxygen, or one of the other 115 currently known elements. For example, most carbon atoms will have 6 protons and 6 neutrons. Atoms of the same element, however, may have different numbers of neutrons in their nuclei. The various forms of an element that differ only in the number of neutrons are referred to as isotopes; one element may have many different isotopes. Some carbon atoms have five, seven, or eight neutrons. Since an isotope is identified by the element name and its atomic weight (i.e., the sum of the protons and neutrons in each atom), carbon atoms with six neutrons in their nuclei (the dominant form) have an atomic weight of 6+6=12 and are referred to as carbon-12. Carbon atoms with five, seven, or eight neutrons in their nuclei are referred to as carbon-11, carbon-13, and carbon-14, respectively. Isotopes of the same element generally have virtually identical chemical characteristics but may differ in other ways. For example carbon-12 is stable whereas carbon-14 is unstable, or radioactive.

Stable isotopes maintain their nuclear structure without changing over time. Radioactive isotopes, referred to as radioisotopes or radionuclides, have unstable nuclei which spontaneously disintegrate and release energy in the process to form other nuclear particles that can be detected by a radioactivity-measuring instrument

There is close cooperation between the various sectors of the U.S. isotopes industry (i.e., the U.S. Department of Energy (DOE), research-oriented universities, and the private sector). The U.S. isotopes industry is characterized by strong government involvement in the production and regulation of isotopes. The DOE, which enjoys unprecedented technical advantages in possessing instrumentation of enormous power and sophistication produces isotopes of critical potential importance, largely for the medical research community. DOE has also played a key role in developing isotope technology, especially in nuclear medicine, complimented by the research programs of universities such as the University of Missouri and Washington University. In comparison, the private industry, including multinational companies such as Covidien, GE Health Care, and Siemens Medical Solutions, has been the dominant producer and/or processor of commercial value-added isotopes for domestic and foreign consumption.

Despite the growing importance of the U.S. isotopes industry, it is nevertheless highly import dependent for the raw isotopes used in end products. The United States currently imports about 90 percent (by volume) of the raw isotopes consumed domestically (including its entire supply of molybdenum-99, the predominant radioisotope used in diagnostic applications), primarily from Canada, the European Union (EU), and Russia. Concern has been expressed by medical researchers about the availability of these radioisotopes as a result of problems experienced in these countries and similar concern was expressed more recently by those in the commercial medical and industrial sectors.

The isotopes industry is globally oriented, with a high degree of international investment and close interrelationships between domestic and foreign isotope companies. This summary covers the isotopes industry primarily for the period 2003-07. It describes the isotope production processes and key end uses, profiles the U.S. and foreign industries and markets, and provides U.S. trade and tariff information for the industry.

Industry Coverage

This summary covers the industry that produces isotopes either artificially or by enriching natural sources of the isotopes.[1] The U.S. isotopes industry (stable and radioactive) consists of private producers, the U.S. government, and universities. In addition, two other sectors are closely related to the isotopes industry–industries that manufacture products containing or requiring radioactive materials and industries that use products made with radioactive materials (such as hospitals and health-care facilities).

The DOE plays an important role in the isotope industry, particularly for research and development (R&D). The U.S. government has become a major developer of nuclear technology since World War II, largely in response to its work on the Manhattan Project and ongoing defense needs. The DOE operates reactors and accelerators capable of producing both radioisotopes and stable isotopes but has limited production (more information on production processes is presented in box 2 and appendix B). DOE is a critically important source of isotopes used in relatively small quantities for research and isotopes that can only be produced in high-energy facilities.

The private industry, in comparison, produces radioisotopes using accelerators only. The private industry can be divided into two categories–companies that predominantly produce isotopes and companies that predominantly use isotopes for incorporation into commercially significant downstream isotopic products such as radiopharmaceuticals. Research-oriented universities also produce isotopes. Unlike private industry, however, such universities produce a variety of isotopes utilizing both nuclear reactors and accelerators, mainly for use in research.

[1] Enriched isotopes have been processed so that, when compared to these same elements that exist in nature, the processed elements contain a higher concentration of atoms with the desired number of neutrons in their nuclei. This subject is discussed in greater detail in the Technical Background section in appendix B. Isotopes of uranium used for fuel or weapons and isotopes of thorium and plutonium are not covered in this summary. The Commission published an *Industry & Trade Summary on Uranium and Nuclear Fuel* in December 1995 (USITC publication 2943).

Box 2. Brief descriptions of some production processes for stable and radioactive isotopes

Stable isotopes are generally "produced" by enriching or concentrating the isotope of interest from sources in which the isotope is naturally found admixed with others. The separation process exploits the different physical properties of the individual isotopes. For example, many of the heavier stable isotopes have been produced by electromagnetic separators known as calutrons. More efficient methods utilizing gas centrifuges, thermal diffusion and cryogenic distillation techniques, however, are said to be replacing calutrons.

Radioisotopes are produced artificially from the bombardment of a stable isotope either with neutrons in a nuclear reactor or with protons or other charged particles in an accelerator. An accelerator is a device that accelerates electrically charged particles to extremely high speeds for the purpose of inducing high energy reactions or producing high energy radiation. The path of the charged particle in an accelerator

Importance of the Isotope Industry

The two main markets for stable and radioactive isotopes are nuclear medicine and industrial applications, with nuclear medicine reportedly accounting for more than half of the total. Nuclear medical procedures have become much more prevalent worldwide. In the United States, they have increased from about 12.9 million in 1997 to an estimated 17.2 million in 2007.[2] Radiopharmaceuticals for diagnostic applications accounted for the largest share of the total in 2007.

In industrial applications, isotopes (primarily radioisotopes) are used in process control including the manufacture of paper, cardboard, beer, spirits, steel strip, and plastics; petroleum refining; petroleum, gas and mineral prospecting; burning of coal for power generation; concrete manufacture; road bed gauging; and in fire safety systems. All these applications form the backbone of the industrial processes and energy production on which our economy depends. Irradiation, a process used to sterilize medical supplies, to treat blood to reduce adverse immunological reactions, and to reduce bacterial levels and minimize spoilage in foods, is another important use. Radioisotopes are also used in smoke detectors and in screening devices used in airports and other transportation facilities to detect explosives and drugs.

Radioisotopes account for the majority of the isotopes used in the United States. Many of the products, particularly those used in nuclear medicine, are specialty products designed and developed for specific uses. Although a major use of stable isotopes is to produce radioisotopes, stable isotopes are also used directly in medical applications (e.g., biomedical research, diagnostic testing such as magnetic resonance imaging (MRI), and therapeutic applications) and in industrial applications (e.g., in nuclear power plants to reduce both unwanted radioactivity and stress corrosion cracking). Stable isotopes employed in industry

[2] National Research Council and Institute of Medicine, "Advancing Nuclear Medicine Through Innovation," 18, 21; and IMV Medical, Inc., Medical Information Division, Inc., "2008 Nuclear Medicine Summary Report."

are generally used in larger volumes, at lower enrichments levels, and are typically less expensive than stable isotopes used in biomedical applications.[3]

Overview of Industry Trends and Developments

The U.S. radioisotopes industry is characterized by extreme import dependence. As discussed more in the section addressing U.S. imports, many radioisotopes critical to medical applications are no longer produced domestically, mainly because of the high costs of production and, to date, the availability of products from foreign suppliers. This has led to concern by many in academia and the private sector about the availability of these isotopes if their importation were halted for any reason, such as an emergency, and about pricing, particularly for research isotopes. Isotopes for research are, at times, either unavailable or priced beyond what the research community can afford.

Also, despite increased use in homeland security, demand for isotopes used in industrial applications has reportedly been declining, largely because of the increasing preference for alternative technologies that do not involve radioactivity (assuming that the replacement technologies are similar in terms of efficacy and cost).[4] A National Research Council report published in 2008, for example, recommends that security-sensitive radioisotopes be replaced with alternate technologies.[5] The decrease in demand has reportedly reduced production by about 3 percent per year, on average, over the past few years.

U.S. INDUSTRY AND MARKET

Industry Structure

As noted, the U.S. isotope industry consists of the DOE, the private industry, and universities. The industry is involved in various stages of processing, from producing the raw radioisotope to manufacturing a finished product such as a radiopharmaceutical. A characteristic of all producers is the need to dispose of low-level radioactive waste. Figure 1 illustrates the flow of radioisotope production, manufacturing, applications, and waste management for an isotope producer or a manufacturer incorporating a radioisotope in their product.[6] Figure 2 is a schematic categorizing some of the key divisions within the isotopes industry.

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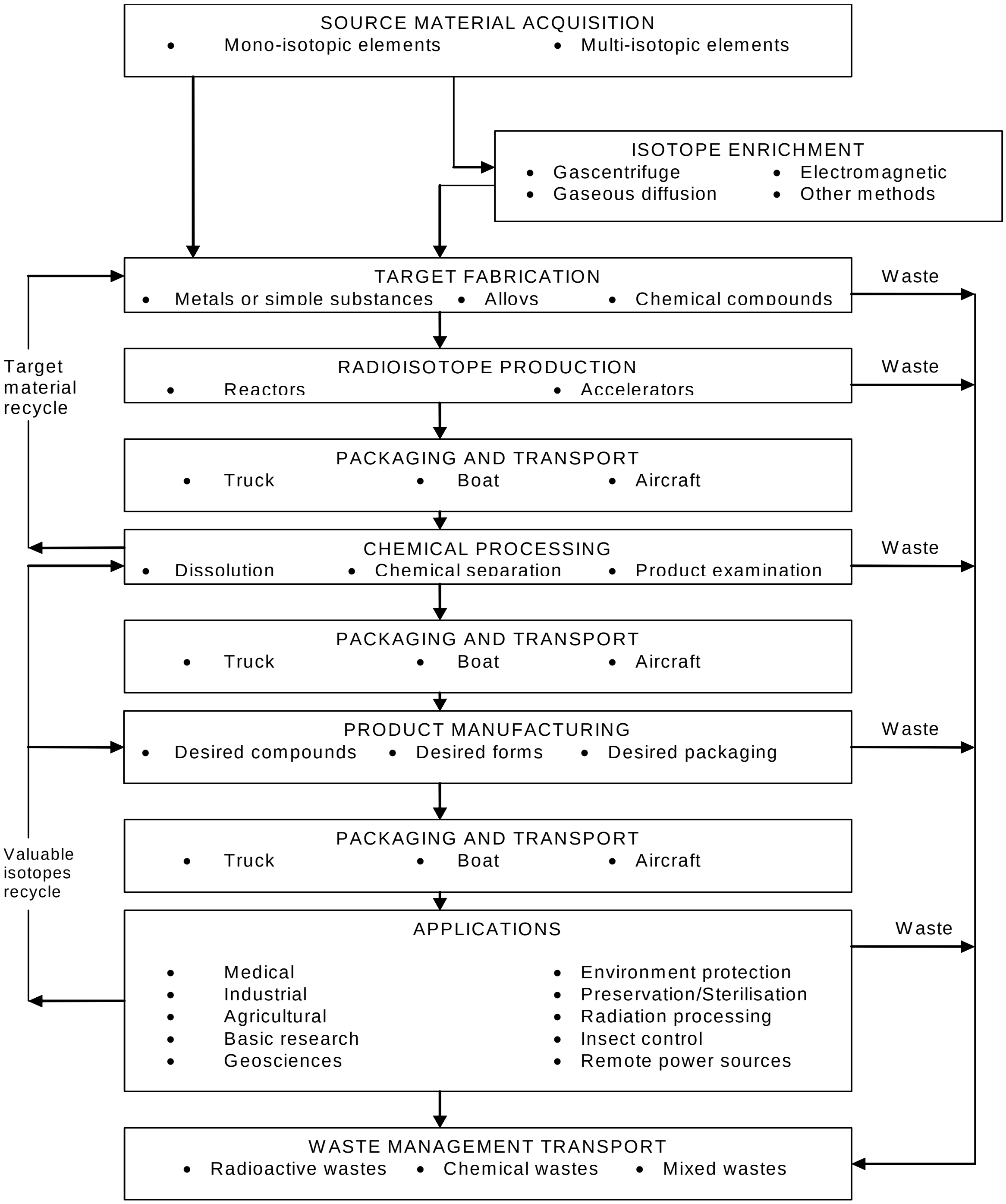
[3] Organization for Economic Cooperation and Development (OECD), Nuclear Energy Agency (NEA), "Beneficial Uses and Production of Isotopes, 2000 Update," 25-28.

[4] OECD, NEA, "Beneficial Uses and Production of Isotopes, 2000 Update," 42.

[5] The U.S. Congress asked the National Research Council (a part of the National Academies) to review civilian uses of radioactive radiation sources and potential replacements for products that pose a high risk to public health or safety in the event of an accident or future attack. The resulting report, published in 2008, recommended that, where applicable, alternative technologies be used to replace such radioisotopes (*Radiation Source Use and Replacement: Abbreviated Version* 2008).

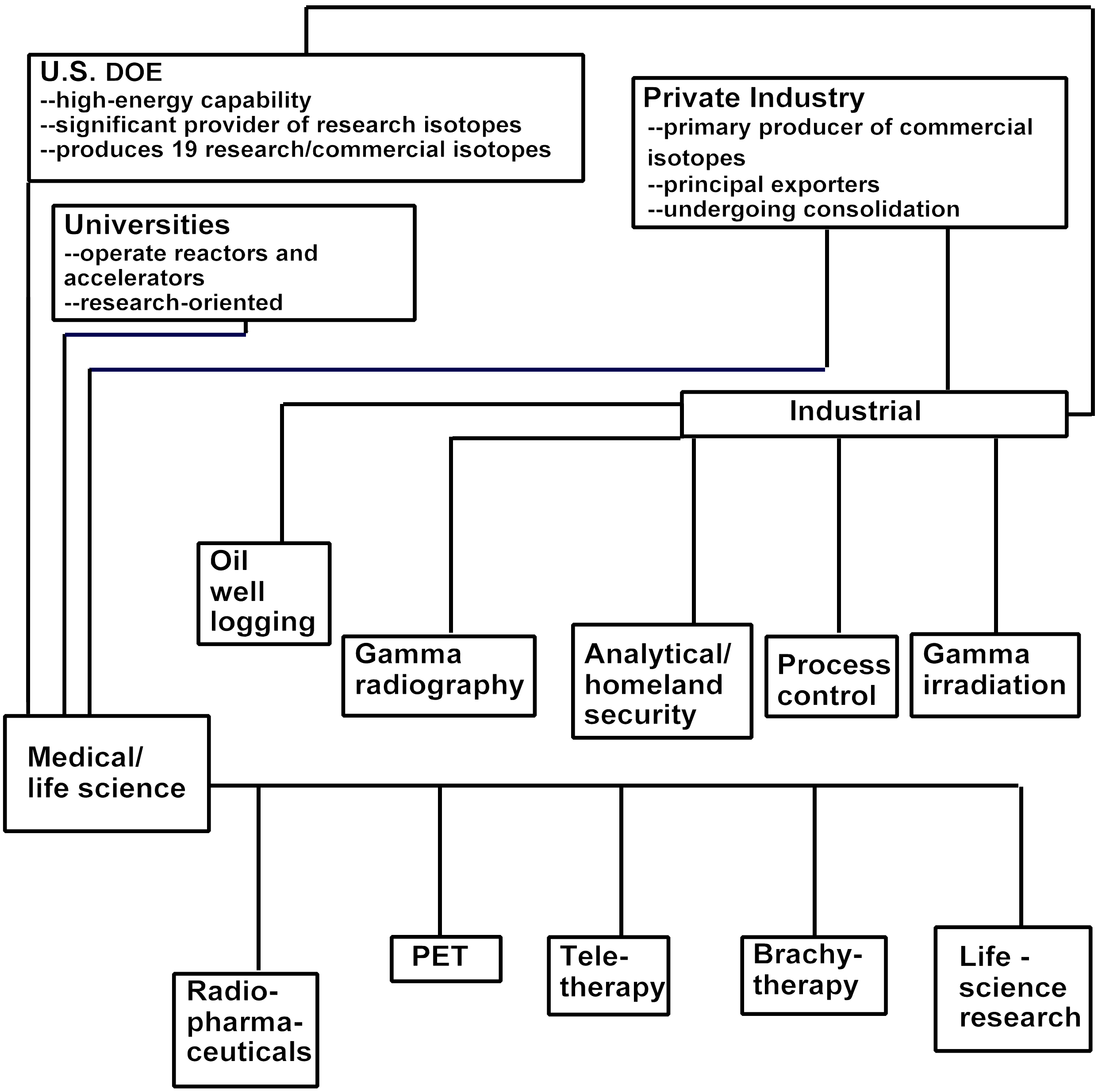
[6] OECD and NEA, "Beneficial Uses and Production of Isotopes, 2000 Update," Figure 1, p 30.

FIGURE 1. Flow of radioisotope production, manufacturing, applications, and waste management



Source: OECD, Nuclear Energy Agency, *Beneficial Uses and Production of Isotopes*, 2000 update, figure 1, p. 30. Reprinted with permission.

FIGURE 2: Structure of the U.S. isotopes industry



Source: Staff interviews with industry sources.

U.S. Department of Energy

Although a number of Federal agencies share responsibility for nuclear matters, the DOE currently retains principal responsibility for most U.S. government activities related to the use of nuclear materials and nuclear instrumentation including reactors and accelerators operated by national laboratories and similar facilities.

In recent years, the DOE's world market share for isotopes was estimated to be less than 5 percent and its share of production of major commercially important isotopes was limited. It remains, as noted previously, however, a critically important source of isotopes used in relatively small quantities for research and isotopes that can only be produced in high-energy facilities (e.g., high-flux reactors, high-energy accelerators, or other specialized costly equipment).[7] In addition to being an isotope supplier, the DOE (and its predecessor agencies) has provided critical R&D for some of the most important advances in the field of nuclear medicine, including the use of the molybdenum/technetium generator and thallium-201, both widely used as diagnostic tools; the development of the Anger scintillation camera, the most widely used imaging device in U.S. hospitals; and the development of Positron Emission Tomography Imaging (PET) (see glossary).[8]

The Isotope Production and Distribution Program (IPDP) was established in 1989 within the DOE's Office of Nuclear Energy to improve the production and marketing of DOE-produced isotopes for commercial and research purposes. The IPDP was established on the condition that its operations were to be financially self-supporting. According to the IPDP, ongoing R&D and upgrades to isotope facilities are currently underway and proceeding as planned.

In fiscal year 2007, the DOE produced 19 research and commercial isotopes. Applications for these isotopes are diverse, and include medical isotopes for cardiomedical imaging (strontium-82), cancer treatment (californium-252 and copper-67), and alleviation of bone cancer pain (tungsten-188/rhenium-188). DOE also produces isotopes for inspecting dangerous or illegal cargo (helium-3, nickel-63, and californium-252), as well as isotopes that may provide environmental information related to global warming (silicon-32) and acid rain (californium-252).[9]

During the past 40 years, however, the DOE and, to some extent, the private industry have ceased producing certain isotopes. Reasons vary but include relatively high production costs; the availability of adequate supplies of isotopes from other countries, especially Canada, the European Union (EU) and Russia; the policy of the DOE not to compete with the private sector; and restrictions imposed on the private industry in operating nuclear reactors. One radioisotope that is no longer produced by the DOE or by any other. U.S. producer in commercial quantities is molybdenum-99, the precursor for technetium-

[7] For example, the Oak Ridge National Laboratory's (ORNL) High Flux Isotope Reactor is one of the most powerful reactors in the United States in terms of steady state neutron fluxes. (DOE, *Report and Financial Statements, Isotope Programs*, 11). The Advanced Test Reactor (ATR) at Idaho National Engineering and Environmental Laboratory and the instruments at Brookhaven National Laboratory and at Los Alamos also rank among the most powerful in the world.

[8] National Research Council and Institute of Medicine, "Advancing Nuclear Medicine Through Innovation," 2007, 24-25.

[9] DOE, Office of Nuclear Energy, "Isotopes for Life."

99m, the most widely-used commercial radioisotope.[10] Although prospects for producing molybdenum-99 in the United States have been under active consideration, likely using advanced technology, no definite plans for resuming molybdenum-99 production on a commercial scale have been announced.[11] Results are pending for an assessment by the National Academies of the technical and economic feasibility of producing molybdenum-99 from LEU.

The DOE has also ceased producing commercial amounts of heavy and light stable isotopes. As the calutrons at Oak Ridge National Laboratory (ORNL) remain on standby, domestic demand for heavy stable isotopes is being met by DOE inventories and, as these are depleted, increasingly from foreign suppliers, especially Russia. According to industry sources, the DOE cannot currently compete with Russian isotope producers for some isotopes because of their low prices.[12] The DOE retains the capability to produce light stable isotopes at facilities located at the Los Alamos National Laboratory in New Mexico, although it has spun off some of its light stable isotope production capacity to the private sector. Domestic demand for light stable isotopes is primarily being met by private sources (including ISOTEC™ in Ohio, a subsidiary of Sigma Aldrich, and Cambridge Isotope Laboratories in Massachusetts) and foreign suppliers.[13]

Universities

In addition to the DOE and private firms, research-oriented universities also produce research isotopes, an outgrowth of academic R&D focusing on nuclear physics and chemistry. Unlike private industry, which produces isotopes principally from accelerators, U.S. universities produce isotopes utilizing both nuclear reactors and accelerators. Universities have been actively cooperating with other parties. For example, the DOE has been supplying some universities with fuel for use in their reactors. In addition, to encourage nonproliferation, the DOE has been providing funding to universities and other institutions to help convert reactors that previously used high enriched uranium (HEU) only (which can be used to make nuclear weapons) to enable them to use high-density but low enriched uranium (which cannot be used in the production of nuclear weapons without further enrichment).[14]

The University of Missouri (MURR), which operates the most powerful university-owned reactor in the United States, is one of the most active institutions in the United States involved with isotope R&D and production, especially related to radiopharmaceuticals. MURR ships isotopes to hundreds of clients in multiple industries. Two radiopharmaceuticals were largely developed by the university–TheraSphere™ (in collaboration with Theragenics Corp.), for treatment of liver cancer, and Quadramet™ (in collaboration with the Dow Chemical Co.), for the relief of pain associated with bone cancer.[15]

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[10] Society of Nuclear Medicine, "Preliminary Draft Report of the SNM Isotope Availability Task Force," June 2008.

[11] Institute of Medicine, *Isotopes for Medicine and the Life Sciences,* 46; and Society of Nuclear Medicine, *Preliminary Draft Report of the SNM Isotope Availability Task Force,* June 2008.

[12] Industry official, telephone interview with Commission staff, October 8, 2008.

[13] ISOTEC™, "*Analytical Services,*" and Cambridge Isotopes Laboratories, "*Products.*"

[14] 2006 Press Release, Argonne National Laboratory.

[15] Ketring, *University of Missouri Research Reactor: Supplying Radioisotopes for Medical Research,* undated.

Washington University in St. Louis, MO, is also very active in isotope production. The university has emerged as a major source of research radioisotopes produced from cyclotrons and is also actively engaged in R&D; one research program has addressed the development of non-standard radioisotopes used in PET.[16] Other universities active in isotope production and research include the University of California at Davis, Texas A&M, Oregon State, Ohio State, Reed College, University of Arizona, and Washington State.[17] The Massachusetts Institute of Technology operates a large research reactor that has been used, in part, to provide short-lived medical isotopes.[18]

Despite the active role of universities in isotope research, concern has been expressed that the universities are not training sufficient numbers of professional workers. Some industry sources claim that there are shortages of both clinical and research personnel in all nuclear medicine disciplines. In particular, according to a recent study, "Training, particularly of radiopharmaceutical chemists, has not kept up with current demands in universities, medical institutions, and industry, a problem that is exacerbated by a critical shortage of university faculty in nuclear chemistry and radiochemistry."[19] University-level courses in isotope-related studies such as radiochemistry were reported to have declined significantly and, in recent years, the number of doctorates awarded in nuclear chemistry, a field closely associated with R&D in isotopes, fell sharply from a peak during 1970-74.[20] An industry source notes that visa quotas and other restrictions on foreign university students and foreign scientists planning to work in the United States may aggravate this trend.

Private Industry

The isotope industry broadly consists of manufacturers, suppliers and users of radioisotopes for medical, industrial, and security applications. The supply chain to the end user includes producers of the radioisotope (using reactors and cyclotrons), companies that process and distribute purified or encapsulated isotopes, and companies that produce and distribute finished products such as radiopharmaceuticals. Several manufacturers and suppliers are vertically integrated.[21] Radiopharmaceuticals and precursor products are produced by large multinational companies as well as by smaller startup companies.

U.S. companies that are significant producers/users of isotopes include Covidien (formerly Mallinckrodt), GE Health Care (formerly Amersham), Lantheus Medical Imaging (formerly part of Bristol-Myers Squibb), Siemens Medical Solutions, Sanders, Perkin Elmer, and Bracco. However, smaller or newer companies have played an increasingly important role in advancing the field. These companies include ISOTEC™, Theragenics Corporation®, Trace Life Sciences, the IBA Group, and many biotech companies. The private industry is also a major exporter of commercial isotopes.

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[16] Welch, Laforest, and Lewis, *Production of Non-standard PET Radionuclides and the Application of Radiopharmaceuticals Labeled with these Nuclides*, January 19, 2007.

[17] "Radionuclides and Radiopharmaceuticals for 2003," *The Journal of Nuclear Medicine*, June 2003, 27N-31N. Also, see Massachusetts Institute of Technology (MIT), "Nuclear Reactor Laboratory."

[18] MIT, "Nuclear Reactor Laboratory."

[19] National Research Council and Institute of Medicine, *Advancing Nuclear Medicine Through Innovation*, citing a 2007 report by the National Research Council entitled *Benchmarking the Research Competitiveness of the United States,* 129.

[20] National Science Foundation, "Survey of Earned Doctorates: 1960-2003."

[21] For example, the following four "raw" radioisotopes are produced by radiopharmaceutical manufacturers: thallium-201, iodine-123, gallium-67 and indium-111. Roy Brown, DOE Workshop, "Importance and Role of Isotopes to the Radiopharmaceutical and Industrial Communities," Aug. 2008.

A new industry has resulted because of the rapid development of PET imaging, a relatively new diagnostic technology which has supplemented older technologies to enhance the detection of diseases. The industry that operates PET centers in the United States is quite distinct from other segments of the radiopharmaceutical industry. These centers, distributed throughout the United States, are operated either by companies that specialize in providing PET scan services or by local medical centers. Because the radioisotopes necessary to perform the diagnosis have a very short half-life, i.e., they decay rapidly, many of the cyclotrons used to produce these radioisotopes are located on site. However, despite this decentralization, most PET isotopes are currently supplied by three companies that operate fairly large cyclotrons in the eastern, midwestern and western portions of the United States–PETNET Solutions, Inc. (PETNET), a subsidiary of Siemens Medical Solutions; Eastern Isotopes (part of the IBA Group); and Cardinal Health. These firms operate distribution systems from which the radioisotope is delivered to medical centers by air or ground transportation. These commercial companies are also actively engaged in R&D.

In the United States, two companies, Sterigenics and STERIS Isomedix Services, operate most of the 29 contract gamma irradiation service centers.[22] Irradiation is a major application for isotopes in which high energy radiation is used to sterilize objects, particularly in the healthcare industry, and to destroy harmful micro-organisms in food and other products. Radioactive cobalt-60, which generates gamma radiation, is the principal isotope for this application. Although other isotopes and non-isotopic sources (e.g., x-ray machines and electron beams) are also used, more than 40 percent of the single-use sterile medical products (such as syringes, IV sets and gloves) manufactured in the United States are treated annually by gamma irradiation.[23] Cobalt-60 is principally supplied by imports, primarily from Canada.[24] A relatively small amount of cobalt-60 is produced by the DOE at the ATR facility in Idaho Falls, Idaho.

Technology Transfer and Partnerships

Technology transfer and globalization in the isotope industry have been facilitated by the proliferation of partnerships, leases, joint ventures, and licensing agreements. In the United States, the DOE, the private sector, and universities have been involved in these type of efforts for decades at both the national and international level.

The DOE has been especially active in entering technology transfer arrangements, in part, because of its mandated responsibilities. For example, the DOE is legally required to cooperate with private sources when feasible to facilitate privatization. Also, as part of the DOE's non-proliferation responsibilities under the Initiatives for Proliferation Prevention, it has developed programs to help scientists in Russia and other republics of the former Soviet Union (FSU) produce marketable products for the civilian sector. Some of these joint ventures are quite complex and involve multiple parties.

Other entities are also establishing cooperative ventures that are reportedly highly diverse, including agreements between private companies and universities, in which the universities agree to supply isotopes to a particular company in return for financial and R&D assistance. Agreements between private companies focus on the different specializations of the

[22] MDS Nordion Corporation (Nordion), "Contract Gamma Irradiation Services by Country."

[23] Gamma Industry Processing Alliance (www.gipalliance.net).

[24] These imports are supplied by Nordion, a privatized Canadian company which is one of the world's largest suppliers of medical isotopes.

individual partners, either in terms of geographic concentrations or the type of services offered.

Market Trends for Radiopharmaceuticals and Brachytherapy[25]

Radioisotopes, particularly radiopharmaceuticals used for diagnostic and therapeutic uses, account for the majority of the U.S. market for isotopes. Strong growth is anticipated for radiopharmaceuticals used in diagnostic applications in nuclear medicine. According to one study, U.S. sales of diagnostic radiopharmaceuticals (including PET), valued at $1.93 billion in 2007, are anticipated to grow by about 11 to 12 percent annually after 2007, reaching $4.06 billion by 2014. Increased use of Single Photon Emission Computed Tomography-Computer Tomography (SPECT-CT) is expected to stimulate demand for many diagnostic radiopharmaceuticals. Growth is also expected to be driven by nuclear cardiology products, especially those used in nuclear perfusion studies coupled with pharmacologic stress agents, and new products for imaging myocardial infarction and congestive heart failure. Sales of nuclear cardiology products are anticipated to grow from about $1.29 billion in 2007 to $2.10 billion by 2014.

PET use itself is anticipated to grow rapidly from an estimated 1.8 million procedures in 2007 to 7.1 million procedures by 2015. Sales of Fluorodeoxyglucose (FDG), the most-widely used radiopharmaceutical for PET, are anticipated to increase from $332 million in 2007 to $1.3 billion by 2015. Use of PET has grown rapidly because of increased use in established areas such as the diagnosis of lymphoma, melanoma, and lung, breast, and colon cancers, and new uses in other areas of oncology. Additionally, PET diagnostic uses are expanding in areas outside oncology, particularly in cardiac imaging applications where Rubidium PET is finding increased use for myocardial perfusion. The use of PET-CT complemented by SPECT-CT (see glossary) is enabling more powerful diagnosis by allowing multiple but non-redundant imaging of the site of interest.

In comparison, the use of radiopharmaceuticals for therapeutic applications is still in the formative stages, with sales in 2005 of about $71 million; these sales are anticipated to increase rapidly, reaching about $1.9 billion by 2012. Most R&D is dedicated to developing radiopharmaceuticals for the treatment of cancers with improved specificity, reduced side-effects, and reduced destruction of healthy cells. R&D efforts in radiopharmaceuticals are proceeding with increased confidence after the achievement of two milestones in radiopharmaceutical development: the FDA granted marketing approvals for Zevalin® and Bexxar®, both used for the treatment of non-Hodgkins lymphoma.

Another area of expected growth in therapeutic applications is in brachytherapy. U.S. sales of brachytherapy products are forecast to grow from about $321 million in 2002 to about $4 billion in 2014. Prostate cancer is a major focus. Prostate seed implants, for example, are performed for about 25 percent of newly diagnosed cases. Brachytherapy is also used to treat

[25] The data and analysis provided in this section are based on news releases available on the Internet accompanying recurrent studies by Marvin Burns of Bio-Tech Systems that examine the U.S. market for radiopharmaceuticals, brachytherapy products and related items.

primary and secondary liver cancers, breast cancer,[26] brain cancer, head and neck cancers, uterine cancer, and cancers that recur frequently. Another application is in treating age-related macular degeneration, which has a large base of patients in our aging population.

Factors Affecting Supply

High capital investment, numerous and stringent federal and state regulations, and other challenges have traditionally posed high entry barriers to the U.S. isotopes industry. Private U.S. isotope producers and processors are characterized by diversity in their size, structure and function. Partly because of the expense and special security concerns,[27] there are currently no known U.S. private producers that produce isotopes in commercial quantities from nuclear reactors that they own and operate.[28]

Isotopes for Healthcare

Radioisotopes produced by the larger radiopharmaceutical manufacturers tend to be ones for which there is already a well-established market. R&D funded by these larger companies tends to focus not on basic research but on developing new carrier molecules for the well-studied radioisotopes, as producers are said to be reluctant to introduce new product lines unless there is evidence of market profitability.[29] According to an industry source, private industry investment in isotopes development and production has been hampered because radiopharmaceuticals are rarely as profitable as some of the "blockbuster" drugs; thus, sales of radiopharmaceuticals are unlikely to generate the revenue required to justify major corporate expenditures.

The private isotope industry has adopted a number of measures to reduce costs and increase efficiency, including increased efforts to track research already done in universities, national laboratories, and the smaller pharmaceutical companies. Typically, a private company relies on research performed by a basic researcher (e.g., at the university level or by research institutions) to determine if the isotope warrants further R&D by the company.[30] One major task the company would then have is to determine how to scale-up production of the isotope.

The radiopharmaceutical industry has undergone significant consolidation through mergers and acquisitions, in part intended to increase the level of vertical and horizontal integration of the major producers. This phenomenon has been characteristic of many companies involved with healthcare. Of particular interest is the teaming up of companies that have a

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[26] The use of post-surgical brachytherapy, introduced in 2001, is also anticipated to grow sharply, especially for breast cancer patients. Sales are expected to increase rapidly beyond 2008 levels as a result of the proven success of accelerated partial breast irradiation and other applications where post-surgical treatment with high dose rate brachytherapy has reduced treatment time with excellent clinical results.

[27] A large nuclear reactor built today will cost hundreds of millions of dollars compared to about $10 million for a large cyclotron. Moreover, the waste products in nuclear reactors have longer half lives resulting in greater waste disposal concerns and expenses.

[28] A small number of private companies own and operate research reactors in the United States. These companies may produce small amounts of radioisotopes for test purposes.

[29] Institute of Medicine, *Isotopes for Medicine and the Life Sciences*, 60-61.

[30] As an example, Washington University's work on isotopes, including making these isotopes available to other research institutions on a low-cost basis, was a determining factor that allowed commercial development of copper-64 and iodine-124 by Nordion and IBA Molecular, respectively (National Research Council and Institute of Medicine, *Advancing Nuclear Medicine Through Innovation*, 2007, 86). Copper-64 is used in the diagnosis of Wilson's disease and the assessment of renal perfusion, whereas iodine-124 is used as a radiotracer in the body.

specialization in medical imaging instruments with radiopharmaceutical companies. This may explain the acquisition of Amersham by General Electric (GE) in 2003 and the acquisition of CTI (including PETNET) by Siemens in 2005.[31] The acquisition of Syncor by Cardinal Health in 2002 is cited as an example of horizontal integration by radiopharmaceutical distributors seeking to attain economies of scale.[32] The industry has also sought to implement cooperative practices to ensure that radiopharmaceuticals are delivered to users in as timely a manner as possible. For example, an industry source noted that radiopharmaceutical producers are contractually obligated to help their competitors obtain radioisotopes for delivery should a cyclotron break down.

Levels of supply are also affected by the inherent qualities of the products themselves. For example, technetium-99m is a natural decay product of molybdenum-99, a radioisotope produced in reactors from the fission of uranium-235.[33] The half-life of technetium-99m is only 6 hours. The half-life for its parent compound, molybdenum-99, is significantly longer (66 hours) but it still decays relatively quickly and needs to be delivered in a timely manner from its production site to the site where the technetium-99m is needed. As such, many nuclear pharmacies and hospitals prepare technetium-99m on site using a generator containing both the parent (molybdenum-99) and the daughter (technetium-99m) isotopes.

Isotopes for Industry

Despite increased use of industrial isotopes in homeland security (e.g., in scanning packages and in explosives detectors), production of industrial isotopes has reportedly declined, on average, by about 3 percent per year over the past few years.[34] Isotopes used in nondestructive testing (radiography) represent an important segment of the industrial isotopes industry. This segment, however, has reportedly undergone significant consolidation, declining from about 10 to 20 firms 20 years ago to 4 or 5 firms, largely because of decreased demand (see following section entitled "Factors Affecting Demand" for more information). Producers of industrial radioisotopes are also facing new administrative burdens following the events of September 11, 2001, including new mandatory requirements and licensing fees. The combination of these factors has reportedly had a substantial detrimental impact on the industry.

Regulatory Challenges

The industry faces a number of major challenges exacerbated by the events of September 11, 2001, which aggravated concerns that terrorists could use radioisotopes in the preparation of "dirty bombs."[35] According to industry sources, new regulations[36] and increasingly

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[31] National Research Council and Institute of Medicine, *Advancing Nuclear Medicine Through Innovation*, 2007, 31.

[32] Industry official, telephone interview with Commission staff, Dec. 21, 2004.

[33] Uranium-235 is the fissionable isotope of uranium.

[34] In terms of industry segmentation, there is not always a clear-cut distinction between isotopes used for healthcare and those used in industrial applications, as some producers manufacture isotopes that are used in both areas.

[35] Although far less lethal than the detonation of a nuclear weapon, the detonation of a "dirty bomb" is considered to be far easier to carry out and could cause wide-spread panic, long-term health problems and major decontamination and rebuilding costs. Only a handful of reactor-produced radioisotopes have been identified as posing the greatest security risks.

[36] For example, the new regulations require applying for specific licenses from the Nuclear Regulatory Commission (NRC) for all exports and imports of radioactive materials. Previously, a general license sufficed which did not require filing of applications to the NRC. IHS Aero-Defense News, "NRC Tightens

stringent enforcement post-September 11, 2001, have resulted in uncertainty, steeper security-related costs for isotope producers, and in some cases, the delay or even loss of time-sensitive radioisotopes, as some airlines have refused to ship radioisotope products.

Even before the events of September 11, 2001, the U.S. isotope industry was one of the most regulated in the United States as a host of federal, state and local agencies exercised jurisdiction over isotopes.[37] Other challenges to the industry relate to the rising costs of bringing new radiopharmaceuticals to the market, the cost of the radiopharmaceuticals themselves (which can be as high as $30,000 or more), and the many costs and regulations involved in the disposal of low level radioactive waste (LLRW).[38]

To improve the efficiency of delivery services, many radiopharmaceutical producers ship isotopic preparations to a central nuclear pharmacy, which prepares the dosage suitable for the patient.[39] The finished radiopharmaceutical is then transported via ground transportation to hospitals and clinics as needed. Monitored by both the Nuclear Regulatory Commission (NRC) and the Department of Transportation, shipping casks used to transport radiopharmaceuticals must undergo tests certifying that they can withstand not only crashes, but also fire, water immersion, and puncture damage.[40]

Another regulatory issue of concern to producers and users of radioisotopes generated from the fission of uranium-235 (including molybdenum-99/technetium-99m) is that under the Schumer Amendment to the Energy Policy Act of 1992, the United States is obligated to bar exports of HEU to foreign reactors unless it is certified that the operator of the facility makes reasonable efforts to eventually change the source material from HEU to low enriched uranium (LEU).[41] The rationale for the legislation is that LEU poses less risks from a proliferation standpoint than HEU, which can be more easily used to make nuclear weapons. This conversion is not, however, a simple matter and some industry sources claim that this conversion mandate is undermining their ability to provide and develop useful medical isotopes. Nevertheless, an industry group which represents manufacturers of radiopharmaceuticals, the Council on Radionuclides & Radiopharmaceuticals (CORAR), indicated that it supports the conversion to LEU where commercially viable but counseled

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Export-Import Regs for Radioactive Materials."

[37] On the Federal level, the NRC regulates the possession, use and handling of radioactive materials; the U.S. Department of Transportation, the movement of radioactive materials; the Environmental Protection Agency, air effluents from a nuclear pharmacy; the Occupational Safety and Health Administration, worker safety; and the Food and Drug Administration, radiopharmaceuticals used internally.

[38] The following materials are classified as LLRW: target materials, contaminated paper, rags and rubber gloves, laboratory equipment, protective clothing and sealed sources. Responsibilities associated with the disposal of low level radioactive waste, which are largely under the control of the States, include ensuring that adequate, safe, economical and equitable LLRW disposal facilities are maintained and anticipating increased demand by providing for expanded or new facilities. (Institute of Medicine, *Isotopes for Medicine and the Life Sciences*, 103-112).

[39] According to the National Association of Nuclear Pharmacies, based on the most current available information, there are 495 nuclear pharmacies operating in the United States. Of these, about two-thirds are operated by health-care companies (Cardinal Health operates 182; PETNET, 42; Covidien, 36; GE Healthcare, 31; Triad, 28; and IBA Molecular, 11). Independent and institutional nuclear pharmacies (96 and 69, respectively) account for the remainder. (National Association of Nuclear Pharmacies, e-mail message to Commission staff, January 14, 2009).

[40] American Nuclear Society, *The Safety of Transporting Nuclear Material, Basic Facts.*

[41] Highly enriched uranium contains 20 percent or more of the fissionable isotope uranium-235, whereas low enriched uranium contains less than 20 percent uranium-235. Uranium which contains 90 percent or more uranium-235, typical of much of the enriched uranium produced by the United States and the former Soviet Union (FSU) during the Cold War, can be used to make nuclear weapons. In order for LEU to pose a nuclear threat, it must be shipped to an enrichment facility and undergo extensive further enrichment.

that it would take time, technical resources, and funding.[42] Also, given the mobility of many radioisotope sources in environments that are not always secure, liability resulting from an accident or malicious act and the role of insurance continues to be a critical issue for the industry. Both the OECD and the International Atomic Energy Agency (IAEA) are attempting to craft a uniform policy regarding the allocation of liability responsibilities.[43]

Some medical researchers expressed their views to the National Research Council and the Institute of Medicine of the National Academies that the regulatory environment in the United States has at times been an impediment to the advancement of medical science. They recommended, among other things, that the FDA address time-consuming regulatory requirements and provide guidelines for "good manufacturing practice" and, that the DOE provide a dedicated accelerator and upgrade reactors to expand isotope production capacity and to cooperate with the National Institutes of Health to increase isotope production and distribution. They also recommended that the research-oriented agencies increase interdisciplinary collaboration regarding technology transfer, particularly related to making technological advances available to the public.[44]

The Potential for Supply Disruptions

Given the foreign dependence of the United States for many isotopes, including molybdenum-99, concern has been expressed about the availability of these isotopes if their importation were halted for any reason, such as an emergency (see discussion of Canada).[45] For example, given DOE's critical role in producing isotopes for research, concern has also been expressed about the ability of the DOE to produce such isotopes in a self-supporting manner, because research needs often demand a large number of isotopes at relatively low volumes for users who have limited funding.[46] Consequently, isotopes for research were, at times, either unavailable or priced beyond what the research community can afford. Although the DOE has many facilities that are capable of producing isotopes, many of these facilities are primarily involved in other applications.[47] As a result, isotope production, especially for smaller customers, is oftentimes of low-priority and can be delayed if production facilities are required for other higher priority projects.[48] There are no DOE accelerators or reactors dedicated exclusively to the production of isotopes, although creation of such a facility was recommended by scientific panels.[49]

One approach the DOE has taken to forestall supply disruption and to advance the state of the art is ongoing collaborations, domestic and foreign, with private and university isotope manufacturers. The cooperation between the DOE and other sectors, especially universities, is one of the salient features of the DOE's outreach program, which has contributed

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[42] Brown, "Importance and Role of Isotopes to the Radiopharmaceutical and Industrial Communities."

[43] OECD, NEA, "Beneficial Uses and Production of Isotopes, 2004 Update," 35-36.

[44] National Research Council and Institute of Medicine, *Advancing Nuclear Medicine Through Innovation*, 2007, 4-8.

[45] Drawbacks to being totally dependent on foreign sources include increased transit time over international borders and adverse consequences resulting from changing production priorities. National Research Council and Institute of Medicine, *Advancing Nuclear Medicine Through Innovation*, 2007, 86.

[46] Institute of Medicine, *Isotopes for Medicine and the Life Sciences*, 13-14.

[47] National Research Council and Institute of Medicine, *Advancing Nuclear Medicine Through Innovation*, 2007, 80-81.

[48] Nuclear Energy Research Advisory Committee (NERAC), Subcommittee for Isotope Research and Production Planning, *Final Report*, April 2000, 14.

[49] National Research Council and Institute of Medicine, *Advancing Nuclear Medicine Through Innovation*, 2007, 7.

significantly to advancing isotope technology. The private sector and academia have also initiated numerous collaborations.

Factors Affecting Demand

Demand for isotopes depends not only upon developments within the field but also upon external developments. In general, if a competing technology does not involve processes that emit radioactivity (i.e., radiation emitted from nuclear decay), it will likely be preferred, assuming that this technology is about as effective as, and similar in cost, to the technology employing the radioisotopes.[50] Even if a competing technology employs potentially harmful radiation such as x-rays, it is often perceived to be safer than radioisotopes, because the penetrating power of x-rays is less than the more powerful gamma radiation emitted during nuclear decay of the radioisotope. A National Research Council report published in 2008 recommends that security-sensitive radioisotopes be replaced with alternate technologies where feasible.[51] Demand may be further depressed by the IAEA's Code of Conduct on the Safety and Security of Radioactive Sources.[52]

According to an industry source, demand for a radioisotope used in bone density measurements has reportedly declined because these diagnostic procedures were replaced, in part, with x-rays. In irradiation, new stringency requirements and concerns have generated technologies that compete with cobalt-60 such as electron beam generators and x-rays. These alternative technologies do not involve radioactive sources and some observers believe that these processes may be considered safer than cobalt-60 irradiation. Reportedly, however, electron beam treatment may not be as effective as cobalt-60 because the penetration of electron beams is less than cobalt-60.

The use of radioisotopes for diagnostic imaging is often complemented by other imaging methods, particularly x-rays, ultrasound, MRIs, and computer tomography (CT), the use of a computer to combine a series of images taken by a camera to create a cross-sectional image. In recent years, an enhanced version of CT, SPECT-CT, which relates molecular imaging to therapy and makes use of radioisotopes, has emerged as a powerful new diagnostic tool for cancer treatment and is anticipated to find uses in other applications.

Shipments, Consumption, and Trade

Estimated U.S. shipments of stable and radioactive isotopes increased from $2.3 billion in 2003 to $3.0 billion in 2007, or by about 30 percent, closely tracking consumption growth during the period (table 1). According to industry sources, the growth in U.S. shipments was attributed primarily to expanded consumption of medical radioisotopes for diagnostic (particularly products used in PET) and therapeutic applications.

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[50] OECD, NEA, "Beneficial Uses and Production of Isotopes, 2000 Update," 42.

[51] The U.S. Congress asked the National Research Council (a part of the National Academies) to review civilian uses of radioactive radiation sources and potential replacements for products that pose a high risk to public health or safety in the event of an accident or future attack. The resulting report, published in 2008, recommended that, where applicable, alternative technologies be used to replace such radioisotopes (*Radiation Source Use and Replacement: Abbreviated Version* 2008).

[52] The International Atomic Energy Agency's (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources introduced a risk based categorization particularly focused on certain major industrially used isotopes.

TABLE 1 Stable and radioactive isotopes: U.S. shipments, U.S. exports of domestic merchandise, U.S. exports for consumption, apparent U.S. consumption, the ratio of imports to consumption, and the ratio of exports to shipments, 2003-07

Year	U.S. shipments	U.S. exports	U.S. imports[a]	U.S. apparent consumption	Ratio of imports to consumption	Ratio of exports to shipments
	Thousands of $				In %	
2003	2,312,000	176,712	237,039	2,135,000	11	8
2004	2,474,000	183,658	257,644	2,290,000	11	7
2005	2,647,000	179,308	253,484	2,468,000	10	7
2006	2,832,000	182,929	289,401	2,649,000	11	6
2007	3,030,000	198,837	301,246	2,831,000	11	7

Source: Compiled from official statistics of the U.S. Department of Commerce and Commission estimates.

Note: Figures may not add to totals shown because of rounding.

[a]U.S. imports are presumed to be inputs for higher value-added U.S. shipments.

U.S. consumption of "raw" isotopes is supplied largely by imports. Industry sources indicate that U.S. imports consist largely of "raw" isotopes with a relatively low level of processing. In contrast, U.S. shipments and U.S. consumption consist primarily of finished products, such as radiopharmaceuticals, that have a high degree of value-added.[53]

As noted by one industry source, imports accounted for about 90 percent by volume of domestic consumption of "raw" isotopes used as inputs for finished products. On a value basis, however, the ratio is considerably smaller given the value-added component of the finished products included in the mix.[54] During 2003-07, the estimated import-to-consumption ratio (by value) remained fairly steady at about 11 percent. The estimated export-to-shipment ratio also remained fairly steady at about 7 percent.

[53] Shipments and trade data at comparable levels of aggregation (e.g., for "raw" isotopes only) are not available.

[54] In general, the cost of the radioisotope itself is only a portion of the cost of producing a given radiopharmaceutical; other expenses include preparing the radiochemical and dispensing the final dose to the patient.

U.S. TRADE

Overview

According to trade data compiled by the DOC, the United States' trade deficit in isotopes increased during the period 2003-07 (table 2).[55] The trade deficit grew from $60 million in 2003 to $106 million in 2006 before declining slightly to $102 million in 2007, an overall increase of 70 percent during the period. Canada, the Netherlands, and Russia accounted for almost 50 percent of total trade with the United States each year during the period. They also accounted for the majority of the deficit; the combined 2007 trade deficit with these countries was $174 million. Significant trade surpluses with Japan, Belgium, and Germany throughout the period slightly eased the trade balance; in 2007, the surpluses with these countries were valued at $24 million, $14 million, and $11 million, respectively, totaling almost $50 million. The annual U.S. trade deficit of between $1 million and $2 million with China during 2003-06 became a surplus of $2 million in 2007.

U.S. Exports

During 2003-07, the value of U.S. exports of stable and radioactive isotopes increased irregularly from $177 million to $199 million (table 2). Shown in figure 3 are the U.S. export shares by major markets for these isotopes. Most of these exports were shipped to Japan, Canada, Belgium, Germany, and the United Kingdom, which are known to posses extensive nuclear medicine facilities (table 2). In general, demand, particularly in foreign markets, is frequently driven by a few major commercial customers.

Although U.S. exports of stable and radioactive isotopes to Pacific Rim countries other than Japan were not large, amounting to only $28 million in 2005, or about 14 percent of total U.S. exports for this product grouping, an industry source predicts that exports (and investments) to this area will likely expand significantly, particularly to China, as healthcare expenditures in that country rise. According to this source, brachytherapy isotopes may be particularly suitable for export as these therapeutic isotopes tend to have longer half lives than other radioisotopes and therefore are not subject to the same time constraints as other radioisotopes with shorter half lives.

U.S. exports and imports are reported separately for only two isotopes –cobalt-60 and heavy water. During 2003-07, U.S. exports of cobalt-60 fluctuated in value between $1.8 million and $4.4 million (table 3). Significant markets for these exports during this period included Mexico, Korea, Germany, Jordan, China, China, Singapore, India, and Japan (appendix table D-1).

During 2003-07, U.S. exports of radioisotopes other than cobalt-60 remained fairly stable in value, ranging between $146 million and $157 million with the largest shipments going to Canada, Belgium, Japan, Germany, and the United Kingdom (table 3, appendix table D-2). According to industry sources, a substantial portion of these isotopes was

[55] The individual export and import classification codes corresponding to the isotopes covered in this report are shown in appendix C.

TABLE 2 Stable and radioactive isotopes: U.S. exports of domestic merchandise, imports for consumption, and merchandise trade balance, by selected countries, 2003-07 (1,000 $)

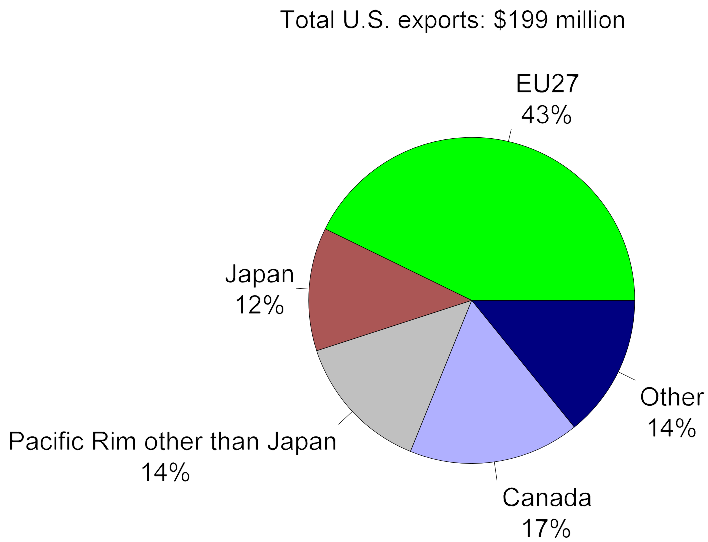
Item	2003	2004	2005	2006	2007
U.S. exports of domestic merchandise:					
Canada	20,921	21,900	22,739	22,298	33,527
Japan	24,666	27,090	27,845	23,117	24,464
Belgium	11,754	15,782	17,536	18,052	23,534
Germany	27,584	29,752	18,335	19,326	21,847
United Kingdom	14,991	9,135	14,021	14,006	16,975
Australia	3,950	5,274	5,367	6,704	6,470
Korea	3,276	4,428	5,548	5,117	6,429
France	4,782	5,742	6,984	6,099	5,174
China	2,933	2,552	3,094	3,133	4,931
Spain	5,305	5,526	5,822	6,847	4,518
All other	56,550	56,477	52,017	58,233	50,968
Total	176,712	183,658	179,308	182,929	198,837
U.S. imports for consumption:					
Canada	97,215	106,908	112,858	144,417	142,054
Netherlands	38,306	46,575	34,467	32,620	41,758
Russia	23,767	25,455	23,887	25,510	26,235
United Kingdom	34,281	31,469	28,910	22,722	19,687
Australia	1,946	4,491	8,136	11,749	16,810
Germany	11,513	8,905	6,345	5,805	10,982
Georgia	1,513	637	4,955	8,842	9,486
Belgium	444	2,420	9,420	6,368	9,438
Switzerland	2,828	3,805	3,463	3,988	4,405
Romania	0	696	221	3,398	3,868
All other	25,226	26,283	20,822	23,982	16,523
Total	237,039	257,644	253,484	289,401	301,245
U.S. merchandise trade balance:[a]					
Japan	24,332	26,799	27,546	22,653	24,115
Belgium	11,310	13,362	8,116	11,684	14,096
Germany	16,071	20,848	11,991	13,521	10,865
Korea	3,224	4,428	5,548	5,110	6,429
Spain	5,305	5,526	5,822	6,838	4,518
Other	37,356	40,806	47,842	47,836	48,155
Subtotal surplus	97,598	111,769	106,865	107,642	108,178
Georgia	-1,513	-633	-4,955	-8,842	-9,486
Australia	2,003	782	-2,769	-5,045	-10,341
Russia	-23,206	-25,054	-23,802	-25,247	-25,762
Netherlands	-29,293	-39,473	-32,502	-30,491	-40,036
Canada	-76,294	-85,008	-90,119	-122,119	-108,528
Other	-29,618	-36,369	-26,897	-22,368	-16,439
Subtotal deficit	-157,921	-185,755	-181,044	-214,112	-210,592
Total	-60,327	-73,986	-74,175	-106,471	-102,409

Source: Compiled from official statistics of the U.S. Department of Commerce.

Note: Figures may not add to totals shown because of rounding.

[a] The trade balance is shown for the top 5 countries with a trade surplus and the top 5 with a deficit.

FIGURE 3. Stable and radioactive isotopes: Export shares by major markets, 2007



Source: Data compiled from tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission.

TABLE 3 Certain stable and radioactive isotopes: U.S. domestic exports, 2003-07 (FAS value, 1,000 $)

Item	2003	2004	2005	2006	2007
Radioisotopes:					
Cobalt-60	1,783	3,704	3,380	4,378	2,742
Other	145,747	157,204	147,916	145,696	154,216
Total	147,530	154,908	151,296	150,074	156,958
Stable isotopes:					
Heavy water	520	853	933	1,109	1,714
Other	28,662	27,897	27,080	31,747	40,165
Total	29,182	28,750	28,013	32,856	41,879
Total	176,712	183,658	179,308	182,929	198,837

Source: Data compiled from trade data from the U.S. Department of Commerce.

radioisotopes commercially made in cyclotrons, including thallium-201, used in heart studies. In addition, although the United States is not a producer of molybdenum-99, industry sources report that U.S. exports of technetium generators, which incorporate technetium-99, presumably generated from imported molybdenum-99, were significant.

U.S. exports of stable isotopes increased significantly in value in 2007. U.S. exports of heavy water rose from $520,000 in 2003 to $1.7 million in 2007 (table 3).[56] The United Kingdom, Korea, Japan, and Germany were the major markets for these exports (appendix table D-3). U.S. exports of other stable isotopes, after holding steady during 2003-05 at about $27-$28 million annually, increased to $32 million in 2006 and to $40 million in 2007. According to an industry source, these exports consisted largely of oxygen-18 used in the production of fluorine-18 for use in PET scans, as well as carbon-13 used in labeling chemicals. The increase likely reflects the growing use of nuclear medicine, including PET scans, in the major markets for these exports–Japan, Canada, Germany, the United Kingdom, France, Austria and Switzerland (appendix table D-4).

In addition to stable and radioactive isotopes, U.S. isotope producers reportedly export significant amounts of "cold kits" to foreign customers. Cold kits are preparations containing the ingredients necessary to prepare a finished radiopharmaceutical minus the radioisotope itself, which can then be added at a later date when needed. Technetium-99m, for example, to be administered to patients in dosage form is often formulated from cold kits. Because cold kits are not radioactive, they may be shipped to a wider area with fewer restrictions and time constraints than the radioisotopes. Cold kits, therefore, are an important element in the supply chain in the production and distribution of isotopes. Because cold kits are not isotopes, the trade data displayed in this report do not reflect trade in these products.

U.S. Imports

As noted previously, the United States is highly dependent on foreign sources for obtaining the raw isotope which is then be incorporated in higher value-added products such as radiopharmaceuticals. During 2003-07, U.S. imports of stable and radioactive imports rose from $237 million to $301 million (table 4). In 2007, Canada was the largest source of these imports (accounting for $142 million, or almost half of these imports), followed by the EU-27 ($89 million, or 30 percent) and Russia ($26 million, or 9 percent) (figure 4). Other than Canada and Russia, the Netherlands ($42 million), the United Kingdom ($20 million) and

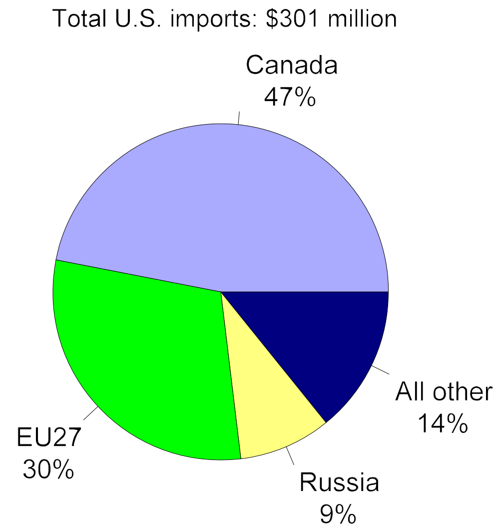
TABLE 4 Certain stable and radioactive isotopes: U.S. imports for consumption, 2003-07 (Customs value, 1,000 $)

Item	2003	2004	2005	2006	2007
Radioisotopes:					
Cobalt-60	22,406	33,962	34,552	40,492	32,897
Other	163,477	178,749	178,124	194,011	217,653
Total	185,883	212,711	212,676	234,503	250,550
Stable isotopes:					
Heavy water	5,080	9,494	6,973	15,317	9,724
Other	46,074	35,439	33,835	39,580	40,971
Total	51,154	44,933	40,808	54,897	50,695
Total	237,039	257,644	253,484	289,401	301,246

Source: Data compiled from trade data from the U.S. Department of Commerce.

[56] Heavy water is ordinary water, H_2O, except that deuterium, a stable isotope of hydrogen, has replaced the two "ordinary" hydrogen atoms. Heavy water in which the ordinary hydrogen atoms have been replaced by tritium is not a stable isotope.

FIGURE 4. Stable and radioactive isotopes: Import shares by major sources, 2007



Source: Data have been compiled from tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission.

Australia ($17 million) were the leading suppliers of isotopes to the United States (table 2). Other significant foreign suppliers of isotopes to the United States include Georgia, Switzerland, Romania, South Africa, China, and Israel. All of these countries are known to have facilities producing isotopes.

Radioisotopes

Cobalt-60 is the only radioisotope covered in this summary for which trade data are individually collected. U.S. imports of cobalt-60, mostly from Canada (Nordion), increased in value from $22 million in 2003 to $40 million in 2006 and then declined to $33 million in 2007 (table 4). Other sources of cobalt-60 during this period included Russia, the United Kingdom, and Argentina (appendix table D-5). The U.S. trade deficit for cobalt-60 (tables 3 and 4) reflects the fact that Canada is a larger producer of cobalt-60 for commercial applications than the United States.

Other than cobalt-60, radioisotope imports covered by this summary are classified in two "basket" or residual categories–HTS subheadings 2844.40.00.20 and 2844.40.00.50 (appendix C).[57] During 2003-07, U.S. imports of radioisotopes provided for in these two categories rose from $163 million to $218 million (table 4). Canada was the largest source of these imports, accounting for $104 million or about 48 percent of total imports in 2007, while imports from the European Union (EU-27) amounted to $68 million or 31 percent of total imports. In 2007, the Netherlands, with imports valued at $33 million, was the second

[57] According to some industry sources, it is possible that some radioisotopes classified under HTS subheading 2844.40.00.50 were misclassified and should have been classified under HTS subheading 2844.40.00.20.

largest single country supplier, followed by the United Kingdom ($20 million), Russia ($18 million), Australia ($17 million), and Belgium ($9 million) (appendix table D-6).

According to industry sources, the principal radioisotope imported classified under HTS subheadings 2844.40.00.20 and 2844.40.00.50 was likely molybdenum-99/technetium-99m. This radioisotope is reportedly exported into the United States by Nordion from Canada, and by Covidien (formerly Mallinckrodt) from the Netherlands utilizing a reactor operated by the European Commission at Petten, and possibly from other sources. During 2003-04, U.S. imports from Canada in these two categories remained at about $70 million, rose slightly to $76 million in 2005, and then increased by 31 percent to $100 million in 2006 and to $104 million in 2007. Factors that could account for the increase during 2005-07 include the increase in medical procedures utilizing these radioisotopes and the higher prices paid by U.S. consumers following the general strengthening of the Canadian dollar during the period.

Radioisotopes imported from Russia used in nuclear medicine reportedly include thallium-201, tellurium-123, cadmium-113, cobalt-60, and strontium-82, a radioactive isotope used to make rubidium-82 generators for cardiac imaging. Although the value of radioisotopes imported from Russia is much smaller than the value of radioisotopes imported from Canada or the EU, these imports reportedly have had a greater competitive impact on the isotope marketing division of the DOE because of their low price. Sources indicate that the low prices are a result, in part, of Russian efforts to obtain foreign currency and maintain employment.[58]

Other countries that supply radioisotopes to the U.S. market include Australia, which reportedly supplies yttrium-90 and germanium-68, and South Africa, which reportedly supplies strontium-82 and strontium-89. Cold kits are imported in significant amounts from a number of countries including Canada, the United Kingdom, and other Western European countries.

Stable Isotopes

As with exports, stable isotopes are broken out into two import statistical reporting numbers–heavy water (used as a moderator in nuclear reactors) and other stable isotopes. During 2003-07, U.S. imports of heavy water, most of which came from Canada and Romania, fluctuated between $5 million and $15 million in value (table 4, also appendix table D-7). Over this same time period, U.S. imports of stable isotopes other than heavy water fluctuated between $34 million and $46 million. Most of these isotopes, in terms of value, originated from Georgia, the Netherlands, Russia, Germany, Israel, Canada, and China (appendix table D-8).

Russia is a major supplier of heavy metal stable isotopes to the United States. One of the most commercially important stable isotopes from Russia is said to be thallium-203, which is converted by cyclotrons in the United States into the thallium-201 radioisotope for use in heart diagnosis.

[58] Industry official, telephone interview with Commission staff, October 8, 2008.

Stable isotopes that are enriched in gas centrifuges are largely imported from Russia[59] and the Netherlands.[60] This technology is considered to be relatively efficient and gas centrifuges could eventually replace the calutrons.

Light stable isotopes imported from Israel reportedly consist largely of oxygen-18, a stable isotope used to produce fluorine-18, which is then used in PET scans. There are two companies in Israel, Marshall Isotopes, Ltd. and ROTEM Industries Ltd., that are known to produce this isotope.[61]

U.S. and Foreign Trade Measures

Tariff Measures

All the isotopes covered by this report enter the United States free of duty from countries eligible for the general or column 1 rate of duty. Imports of isotopes enter under various tariff subheadings in chapter 28 of the Harmonized Schedule (HS) (appendix C).

Many foreign markets, however, impose duties on imported isotopes. The following tabulation shows the duties (or the average duties) in percent ad valorem on isotopes for normal trade partners for the EU and a number of commercially important countries. In several instances, the duties are different for radioisotopes and stable isotopes (including heavy water) and therefore duties for these categories are reported separately.

The United States enjoys a significant competitive advantage exporting isotopes to Mexico under the provisions of NAFTA given the relatively high 13 percent duty for exports to Mexico from non-NAFTA countries. Generalizing, the foreign duties shown appear to indicate that tariff barriers in developing countries can be significant but are less so in developed countries.

[59] Springer Science and Media, P.V. Publishers,"Application of Stable Isotopes in Russian Federation."

[60] Imports of stable isotopes from the Netherlands are believed to be, at least in part, imports supplied by Urenco, a consortium with facilities in the Netherlands, the United Kingdom, and Germany that specializes in uranium enrichment from gas centrifuge technology. According to publications, Urenco supplies zinc-68, cadmium-112, and xenon-124 used in diagnostic, therapeutic applications, or imaging (See http://www.urenco.com and http://www.isotopetrace.com).

[61] See the websites of Marshall Isotopes Ltd. and ROTEM Industries Ltd.

TABLE 5 Most favored nation tariff rates for selected countries (% ad valorem)

Country	Radioisotopes	Stable isotopes (including heavy water)
Brazil	6	2
Canada	0	0
China	4.5	5.5
EU	0	5.5
India	12.5	12.5
Mexico[a]	13	13
Japan	0	0

[a]U.S. exports of radioactive and stable isotopes to Mexico are duty-free under NAFTA.

Source: International Customs Tariff Bureau (2008), the World Trade Organization, and country-specific tariff schedules.

U.S. Nontariff Measures

The United States imposes numerous restrictions on the movement of radioactive materials for safety and security purposes. Many of these measures originated in the IAEA and have been incorporated into U.S. laws and regulations. Superimposed on these are additional layers of U.S. laws and regulations, especially those promulgated by the FDA. Industry sources have cited instances where similar but slightly different regulations between the United States and other countries have resulted in unnecessary duplication and, in some cases, forced these companies to forgo market opportunities either in the United States or in other countries. These sources have also cited unnecessary delays and excessive red tape when an imported product was only slightly modified. Also of concern, as noted previously, was the new climate following September 11, 2001, when tightened security oversight resulted, in some cases, to lost merchandise. Industry groups such as CORAR, the industry association for the medical radioisotopes industry, is discussing these issues with applicable federal, state, and local government authorities in order to find a proper balance between the new heightened security concerns and the needs of radioisotope consumers particularly in the medical area.

Foreign Nontariff Measures

Industry sources contacted by Commission staff reported a number of trade barriers that affect exports of isotopes, including issues related to intellectual property rights (IPR), restrictive national laws, limitations on the types of aircraft that are allowed to transport isotopes, national regulatory environments, and customs practices. For example, according to one industry source, trade barriers in South America included weak IPR and competing counterfeit products. In Mexico, industry sources cited customs problems and a lack of consistency. Consequently, importing a radioisotope shipment into Mexico reportedly can take up to 3 days, a critical concern given the time sensitivity of many radioisotopes. In Japan, marketing regulations are said to have made the product approval process difficult and lengthy. A U.S. exporter reported that in India a special import license has been required certifying that the exported isotope is not produced in India. According to another source, Russia hasn't allowed many radioactive materials to be imported, reportedly to bolster its domestic industry. Additionally, according to an industry source, the Brazilian government has imposed restrictions on non-government entities marketing isotopes, thereby limiting physicians' access to radiopharmaceuticals supplied by producers located outside the country.

The IAEA has identified numerous trade barriers for isotopes, including "problems and delays in transport of radioactive materials; the need for compliance with transport regulations; {and} the denial of shipments by some carriers." The IAEA also cites "the practice of holding up all the cargo in airports at times for a pre-destined period (say 24 to 48 hours) before being loaded on a plane, as part of measures for enhancing security" as being detrimental to the critical need for the rapid transport of medical isotopes.[62]

FOREIGN INDUSTRY PROFILES

As in the United States, isotope producers worldwide, whether government entities, private sector firms, or universities, face high barriers to entry. The role of government is important as producers in all sectors are often dependent upon government facilities for raw materials and their income may derive, in part, from collaborative agreements between the producer and a government entity.[63] In general, public entities (governments and universities) own and operate research reactors and large accelerators used in isotope production, whereas private firms frequently own and operate medium and small-scale accelerators.[64] A privatization trend throughout the global industry may result in private firms owning and operating an increasing number of facilities. Whereas large multinational companies operate the facilities that account for most Western isotope production, according to an industry source, their decisions regarding the location of their operations worldwide are based upon economic considerations, such as the impact of applicable regulations, expenses incurred, time to delivery to markets, logistic capability, and likely level of reimbursements.

Figure 5 displays the worldwide distribution of isotope production facilities by category.[65] Cyclotrons, both for PET and other medical isotopes, account for the majority. Worldwide, there are reportedly about 250 cyclotrons that produce isotopes in 34 countries, of which several dozen are operated by radiopharmaceutical companies dedicated to isotope production. Other than those facilities dedicated to isotopes, the other reactors are largely utilized in multiple applications, including research.

Canada

Canada is a major producer and supplier of molybdenum-99/technetium-99m to the United States, which, as noted previously, is not produced in commercial quantities domestically. The producer of this material is Atomic Energy of Canada Ltd. (AECL), a Canadian Government-owned corporation that operates a reactor (the National Research Universal

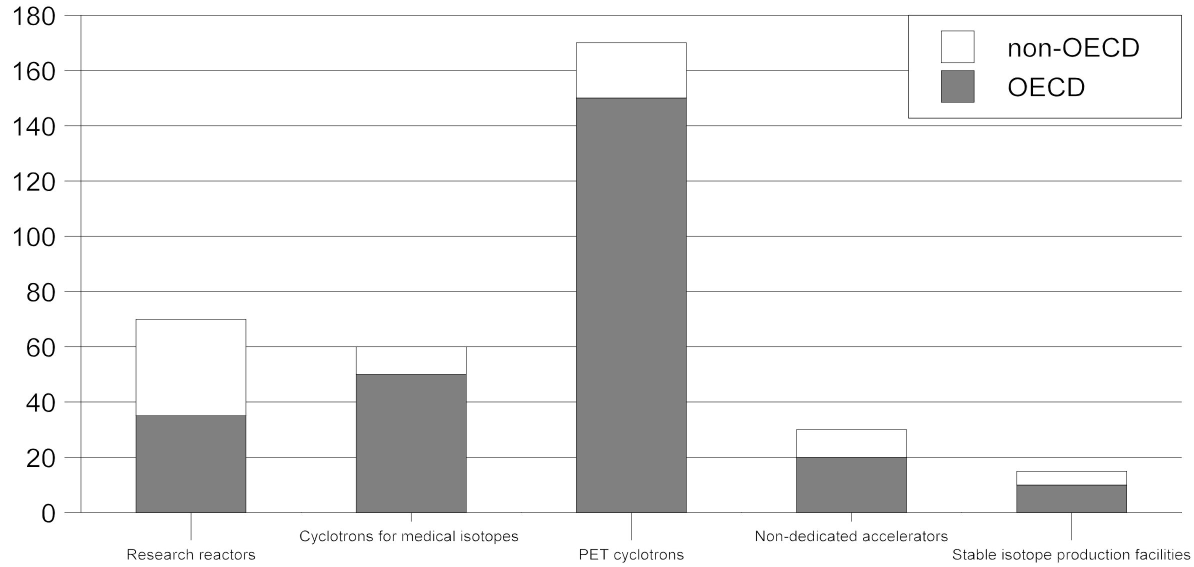
[62] The IAEA, "Radiopharmaceuticals: Production and Availability."

[63] The Nuclear Energy Agency of the OECD has highlighted what it believes should remain the key responsibilities of governments in order to maintain a viable isotope industry: These include facilitating cooperation among interested parties, providing adequate resources for the production of R&D isotopes, monitoring the need of researchers and clinicians, facilitating privatization, and addressing concerns about foreign dependence, especially in situations where supply interruptions are unacceptable. OECD, NEA, "Beneficial Uses and Production of Isotopes, 2004 Update," 34-35.

[64] OECD, NEA, "Beneficial Uses and Production of Isotopes, 2000 Update," 6.

[65] A listing of isotopes, including their country of manufacture and mode of production, is provided in the appendices to the OECD's report, entitled "Beneficial Uses and Production of Isotopes, 2004 Update."

Figure 5. Number of isotope production facilities in OECD and non-OECD countries by category



Source: OECD, Nuclear Energy Agency, *Beneficial Uses and Production of Isotopes*, 2000 update, p. 31. Reprinted with permission.

(NRU) reactor) producing molybdenum-99 in Chalk River, Ontario. AECL also operates other research reactors in Canada. The entity responsible for marketing molybdenum-99 is MDS Nordion, a privatized company and a subsidiary of MDS Inc., Canada's largest healthcare company and the world's largest supplier of medical isotopes.[66] Nordion has processing facilities in Ottawa, Ontario, and in Vancouver, British Columbia, as well as overseas, in Fleurus, Belgium. Nordion currently operates several cyclotrons and has access to reactors, but does not own or directly operate them. To address concerns about the continued availability of molybdenum-99 and other radioisotopes, especially as the NRU reactor is aging, Nordion had ordered two small specialized reactors (MAPLE reactors) at Chalk River; however, these projects appear to have been cancelled as indicated below.[67] Nordion is also upgrading its cyclotron facilities in Vancouver. Other isotopes supplied by Nordion include indium-111, palladium-103, gallium-67, strontium-82, iodine-123, and iodine-125.

An important factor in Nordion's success is its partnership with the four local universities operating the Tri-University Meson Facility (TRIUMF)–the University of British Columbia, the University of Alberta, the University of Victoria, and Simon Fraser University. Nordion benefits from being the sole commercial supplier of isotopes produced at TRIUMF. The facility not only includes one of the world's largest cyclotrons, but also has a strong research program in both basic and applied research on isotopes, and has entered into a 30-year

[66] As of 2004, MDS Nordion supplied over two-thirds of the world market in radioisotopes. Elford and D'Auria, Nuclear Physics News, "An Overview of the Radiopharmaceutical Industry," 34.

[67] A longer than expected shutdown of the Chalk River facility as a result of maintenance problems at year-end 2007 had resulted in shortages of molybdenum-99. This has caused the postponement of some diagnostic tests in hospitals and underscored the vulnerability of North American consumers of medical radioisotopes who are highly dependent on this one facility. Austen, *New York Times*, "Reactor Shutdown Causing Medical Isotope Shortage," Dec. 6, 2007.

technical support agreement with Nordion.[68] Some analysts have stated that this relationship could serve as a model for successful business-university cooperation that the United States should consider emulating, at least in part.[69]

The United States, which currently provides Canada and other countries with HEU targets for the production of radioisotopes, has helped foreign isotope producers switch to LEU targets in their facilities for non-proliferation reasons. Some companies, however, have expressed reluctance to switch sourcing because of concerns about potential delays, technical problems, and expenses.[70] Others have reevaluated plans. In May 2008, for example, AECL announced that it had decided to immediately discontinue development on its two MAPLE research reactors at its Chalk River Laboratories in Ontario citing as one reason, uncertainties about the continued viability of producing medical isotopes from HEU in light of growing opposition to using HEU.[71] AECL said that its decision to discontinue development of the MAPLE reactors will not impact the current supply of medical isotopes as commercial agreements between Nordion and AECL provide for isotope production to continue through AECL's 135 MW NRU reactor and associated facilities in Chalk River.[72] However, an industry observer noted that the lifetime of the aging NRU reactor is limited and may not go beyond 2015.[73]

EU-27[74]

The EU-27 countries account for the majority of European isotope production and consumption. In the Netherlands, Covidien (formerly Mallinckrodt) operates two cyclotrons and procures isotopes produced in a reactor in Petten in the Netherlands owned by the European Commission. With isotopes produced or supplied from its European operations as well as in the United States, the company has become a significant player in the world market and the U.S. market as well.[75] Canadian-based Nordion has also become a major European player, producing yttrium-90 at facilities located at Fleurus, Belgium. A third major commercial-based producer is GE Healthcare. In Europe, GE Healthcare is largely based in the United Kingdom and Germany. Significant quantities of isotopes are produced by research reactors in the Netherlands, Belgium, the Czech Republic, France, Hungary, Poland, Sweden, Norway, Portugal, Ukraine, Italy and Romania.[76] Urenco, a British-Dutch-German consortium, is a supplier of stable isotopes produced in its gaseous centrifuge enrichment facilities. Eastern Europe lags its Western Europe counterparts but is expected to reduce the gap as its healthcare infrastructure improves.

[68] Institute of Medicine, *Isotopes for Medicine and the Life Sciences*, 66-67.

[69] Ibid.

[70] *Nuclear Fuel*, “Nordion Headed for ‘Showdown’ with U.S.?,” March 15, 2004, 1, 14-16.

[71] *Inside NRC*,“Questions About Future of HEU had Role in Maple’s End, AECL Says,” May 26, 2008.

[72] *World Nuclear News*, “AECL Halts Development of MAPLE Project,” May 19, 2008.

[73] Ruth, “World View of Radioisotope Production,” August 5, 2008; AMIC Press Release, “AECL Aborts Development Work on MAPLE Medical Isotope Reactors, May 16, 2008.

[74] The EU-27 member states are Austria, Belgium, Bulgaria, the Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, and the United Kingdom.

[75] As of 2004, Mallinckrodt (currently Covidien) was the second largest commercial producer of medical radioisotopes with an estimated radiochemical market share of 25 percent. Elford and D’Auria, “An Overview of the Radiopharmaceutical Industry,” 2004, 34.

[76] OECD, NEA, “Beneficial Uses and Production of Isotopes, 2004 Update,” 39-41.

Russia

Russia and other republics of the FSU are among the world's largest producers of isotopes, particularly industrial isotopes.[77] Stemming from its historic role in developing nuclear programs for both military and domestic use, Russia has developed production capacity for a broad range of radioactive and stable isotopes. As military needs have declined, much of this capacity has been redirected to producing isotopes for commercial exports. Russian facilities for producing radioisotopes include reactors located at Dimitrovgrad, Moscow, Mayak, and Gatchina and accelerators located at St. Petersburg, Troitsk, Moscow, and Obninsk.[78] Typically, these producers, now privatized, are engaged in the production of commercial isotopes to allow the facilities to continue operating and to generate income for their employees.

Russia is one of the leading global producers of stable isotopes, with calutrons located at Sverdlovsk and centrifuges located at Zelenogorsk.[79] One industry source reports that Russia is now the leading supplier to the United States of heavy stable isotopes, given the DOE's reduced production of those products. The ability of Russian isotope producers to expand markets has reportedly been aided by low prices (reportedly the result of factors such as relatively low labor costs and a large inventory of defense-related raw materials) and by wide-spread cooperation with Western companies.

Distributors of these isotopes include U.S. companies, such as Cambridge Isotope Laboratories, that have set up joint ventures with several Russian firms as well as domestic alliances. REVISS, for example, is a joint venture between UK Amersham (now part of GE Healthcare), the Russian nuclear firm Mayak, and the Russian export company, Techsnabexport. According to a reference cited in a study sponsored by the Monterey Institute, Center for Nonproliferation Studies, the Russian Ministry for Atomic Energy reportedly has been trying to increase Russian exports of cobalt-60 from about 25 percent of the world market in 2000 to 40 percent.[80] The study indicates that other reactor produced isotopes produced in Russia and supplied by REVISS are cesium-137, strontium-90, americium-241, and iridium-192. MDS Nordion also has purchasing agreements with Russian producers of cobalt-60.

Other Countries

Other countries that produce and export isotopes include South Africa, Australia, Israel, China, and Argentina. In South Africa, the i-Themba Laboratory for Accelerator-Based Sciences specializes in accelerator-produced isotopes, whereas the South Africa Nuclear Energy Association operates a reactor (Safari-1) that produces molybdenum-99 and iodine-131. South Africa has exported a limited amount of molybdenum-99/technetium 99m to the United States in the preparation of technetium-99 generators. The Australian Nuclear Science & Technology Association operated a reactor that produced iodine-131, iridium-192, and samarium-153. Australia is installing a new reactor dedicated to R&D and isotope production. In Israel, two companies specialize in producing oxygen-18, a stable isotope

[77] With the exception of cobalt-60, most industrial isotopes used in the United States are imported from Russia.

[78] Ibid., 41, 50.

[79] Monterey Institute, Center for Non-proliferation Studies, "NIS Nuclear and Missile Database."

[80] Monterey Institute, "Commercial Radioactive Sources: Surveying the Security Risks," 37-38.

used to produce fluorine-18, the principal radioisotope used in PET. In China and Argentina, reactors are used to produce commercial isotopes including cobalt-60 for domestic and export applications.

FOREIGN MARKETS PROFILE

The largest market for isotopes is the United States (which accounts for about half the global market), followed by the EU and Japan. There has, however, been some market shift from North America and Western Europe to Eastern Europe and China prompted by the latter regions' lower costs "and/or their highly subsidized operating modes."[81] Rapid growth in demand is also expected in areas that are investing heavily in improving their medical infrastructure (e.g., China, India, and the Gulf states).

According to an industry source, channels of distribution for radiopharmaceutical producers outside the United States differ from those within the United States in that the role of nuclear pharmacies is not as well-established abroad. In countries with nationalized healthcare, the government is the buyer and distributor of radiopharmaceuticals. In Japan, because of its relatively small land area and dense population, radiopharmaceuticals are reportedly generally delivered directly from the manufacturing facility to hospitals and clinics.[82] By contrast, in Europe, industry sources report that nuclear pharmacies, although not as prevalent as in the United States, are becoming more widespread. Hospitals and clinics reportedly increasingly prefer the convenience of these establishments, which relieve them of the burden of preparing radiopharmaceutical preparations on-site.

[81] OECD, NEA, "Beneficial Uses and Production of Isotopes, 2000 Update," p. 47.
[82] Ibid.

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APPENDIX A
Technical Glossary

TECHNICAL GLOSSARY[83]

Accelerator—A device that accelerates electrically charged particles to extremely high speeds, for the purpose of inducing high energy reactions or producing high energy radiation.

Antibody—A protein made by the immune system to detect and destroy foreign intruders.

Atom—The basic building block of matter. An atom consists of a nucleus which is surrounded by electrons. The nucleus consists of positively charged protons and neutrons which have no net charge. The electrons, which are much lighter than the protons or neutrons, have a negative charge equal in magnitude to that of the protons. In the neutral atom, i.e., an atom having no net charge, the number of protons and electrons is equal.

Brachytherapy—The use of low-dose or high-dose sealed radioactive sources strategically implanted in the body to destroy tissue that is harmful.

Cold kits—preparations containing the ingredients necessary to prepare a finished radiopharmaceutical, minus the radioisotope itself (which can then be added at a later date when needed).

Computer Tomography (CT)—A diagnostic imaging technique that uses specialized X-ray equipment to obtain image data from different angles, followed by computer processing of the information to show a cross-section of tissues and organs.

Cyclotron—A circular accelerator in which an alternating electric field is used to accelerate charged particles spirally outward. Most accelerators used commercially in medical and industrial applications are cyclotrons.

Element—One of the more than 100 types of substances that make up matter. The element in which a given atom is classified is determined uniquely by the number of protons in its nucleus.

Fission—The break-up of the nucleus of an atom into two major fragments, plus smaller fragments and free neutrons, when the nucleus is struck by a fast-moving free neutron.

Gamma rays—An energetic form of electromagnetic radiation emitted during the decay of the nucleus of a radioisotope. The radiation pattern can be measured by instruments such as gamma cameras to form an image.

Half-life—The time required for an radioisotope to disintegrate so that half its atoms have decayed. The half-life is a statistical constant for a given radioisotope and is independent of physical conditions.

[83] These definitions were obtained from various sources including the Institutes for Medicine's report, "Isotope and the Life Sciences," (1995); the National Research Council and Institute for Medicine's 1997 report, Advancing Nuclear Medicine through Innovation, and material obtained through an Internet search.

Highly enriched uranium (HEU)**-**Uranium that has been enriched such that the fissionable isotope uranium-235 accounts for 20 percent or more of the final product. HEU is often preferred over low-enriched uranium (LEU) as a source for isotopes produced from the fission of uranium because of technical and economic advantages. However, HEU raises proliferation concerns since it can be more readily used to make nuclear weapons.

Immunotherapy–Therapeutic treatment that involves stimulating, enhancing, or suppressing the ability of a person's immune system to fight infection and disease.

Isotope—A component of an element whose atoms contain a fixed number of neutrons. Most elements consist of a mixture of isotopes.

Low enriched uranium (LEU**)-**Uranium that has been enriched such that the fissionable isotope uranium-235 accounts for less than 20 percent of the final product. LEU is preferred as a source for isotopes that are produced from the fission of uranium (versus HEU) because it cannot be used to make nuclear weapons without further enrichment.

Monoclonal antibody—An antibody (see) derived from a single cell in large quantities for use against a specific protein, especially used in the diagnosis and treatment of cancer.

Nuclear Medicine—A branch of medicine in which radioactive atoms and molecules (i.e. radioisotopes) are used in the diagnosis and treatment of disease and in research.

Nuclear reactor—An apparatus in which a controlled nuclear fission (see) chain reaction takes place. Typically, the chain reaction is initiated by a source of neutrons.

Positron Emission Tomography (PET**)** ***Imaging***—A relatively new form of imaging based on the phenomenon that radioisotope decay may involve the release of positrons. A positron is a form of antimatter which has the same mass as an electron but with equal and opposite charge. Positrons are short-lived because they react instantaneously with a nearby electron to produce two gamma rays traveling in opposite direction.

Radioisotope or ***radionuclide***—An isotope whose nucleus is not stable. Upon disintegration of the nucleus, energy is released in the form of particles and electromagnetic radiation.

Radiopharmaceutica**l—**A radioactive drug comprising a radioisotope and a pharmaceutical that is used for diagnosis or therapy.

Single Photon Emission Computed Tomography-Computer Tomography (SPECT-CT)—A hybrid imaging system which allows metabolic and functional information derived from SPECT (a type of radioactive emission associated with radioactive decay) to be combined with the high spatial resolution and anatomic information of CT.

Target—A substance that is bombarded by neutrons in a reactor or by charged particles in an accelerator such that some of the nuclei of the target have been transmuted into another element or isotope. Typically, the bombarded target has been transmuted into a useful product such as a radioisotope used in medicine, industry or research.

APPENDIX B
Technical Background

Technical Background

Matter is composed of atoms with nuclei containing protons and neutrons. It is the number of protons in the nuclei that determines whether the atom is hydrogen, carbon, uranium, oxygen, or one of the other 115 currently known elements. Atoms of the same element, however, may have different numbers of neutrons in their nuclei. The various forms of an element that differ only in the number of neutrons are referred to as isotopes; one element may have many different isotopes.[1] Isotopes can be either stable or radioactive. The former maintain their nuclear structure without changing over time. The latter, referred to as radioisotopes or radionuclides, have unstable nuclei which spontaneously disintegrate and release energy in the process to form other nuclear particles that can be detected by a radioactivity-measuring instrument such as a geiger counter.

Stable isotopes are generally "produced" by enriching or concentrating the isotope of interest from sources in which the isotope is naturally found admixed with others. The separation process exploits the different physical properties of the individual isotopes. For example, many of the heavier stable isotopes have been produced by electromagnetic separators known as calutrons.[2] These instruments separate isotopes from a mixture by relying on the fact that the tracks of different isotopes placed in an appropriately designed electromagnetic field are different and, as such, can be collected separately. Alternatively, for heavy elements that can form gaseous compounds, the material is spun in a gas centrifuge at a sufficiently high speed conducive to the separation of the heavier isotopes from the lighter ones.[3]

Stable isotopes are used in biomedical research in areas such as metabolism, congenital diseases, osteoporosis, diabetes, and psychiatric, cardiac, and pulmonary diseases.[4] Stable isotopes are also used in industry, especially in nuclear power plants where they are used to reduce unwanted radioactivity and to reduce stress corrosion cracking. Stable isotopes employed in industry are generally used in larger volumes and at lower enrichments levels, and are typically less expensive than those used in biomedical applications.[5]

Examples of stable isotopes and their direct applications include rubidium-85 and rubidium-87 used in mental illness research; helium-3 and xenon-129 used in MRI; and carbon-13, used as a tracer. Heavy water is a commercially important form of water (H_2O) in which the "normal" hydrogen atoms have been replaced by a heavier stable isotope of hydrogen, deuterium. Heavy water is primarily used as a moderator in nuclear reactors.

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[1] Carbon atoms, for example, have six protons in their nuclei. Whereas most carbon atoms also have six neutrons, others have five, seven, or eight. An isotope is identified by the element name and its atomic weight (i.e., the sum of the protons and neutrons in each atom). Thus, carbon atoms with six neutrons in their nuclei (the dominant form) have an atomic weight of 6+6=12 and are referred to as carbon-12. Carbon atoms with five, seven, or eight neutrons in their nuclei are referred to as carbon-11, carbon-13, and carbon-14, respectively. Isotopes of the same element generally have virtually identical chemical characteristics but may differ in other ways. For example carbon-12 is stable whereas carbon-14 is not.

[2] Although some lighter stable isotopes can be produced by electromagnetic separation techniques, more efficient methods include gas centrifuge, thermal diffusion and cryogenic distillation techniques. The use of calutrons has been largely phased out in the United States.

[3] Instruments that can separate the heavier stable elements are of special concern because these same instruments can be used to produce fissionable materials.

[4] Organization for Economic Cooperation and Development (OECD), Nuclear Energy Agency (NEA), "Beneficial Uses and Production of Isotopes, 2000 Update," 25-27.

[5] OECD, NEA, "Beneficial Uses and Production of Isotopes, 2000 Update," 28.

Many stable isotopes, however, are primarily produced to serve as a starting material for the production of radioisotopes. Radioisotopes are produced artificially from the bombardment of a stable isotope either with neutrons in a nuclear reactor or with protons or other charged particles in an accelerator. The path of the charged particle in an accelerator may be linear, as in a linear accelerator, or spiral, as in a cyclotron. Alternatively, some radioisotopes are recovered as a byproduct from the fission (decay) of uranium and other radioisotopes.

Although all radioisotopes disintegrate over time, there is an enormous range in how rapidly such decay occurs; some radioisotopes disintegrate so slowly that they are considered practically "stable," whereas others will effectively vanish in a manner of minutes. To measure the relative stability/instability of radioisotopes, scientists employ the concept of "half-life," the time required for one-half of the isotope initially present to decay to other nuclear forms. The half-life is a statistical constant for each radioisotope. Table B-1 lists selected radioisotopes, their principal uses, their half-lives, and a brief description of how they are made.

TABLE B-1. Characteristics of selected radioisotopes

Radioisotope	Half-life	Production method	Uses
Americium-241	432 years	Nuclear reactor decay product of plutonium-241	Smoke detectors, assessment of petroleum wells
Cesium-137	30 years	Uranium-235 fission product	Cancer treatment, to measure and control liquid flows in petroleum pipelines, and to ensure correct fill levels for packages
Cobalt-60	5.3 years	Reactor product from stable cobalt-59 as the target	Sterilization of medical supplies, food irradiation, and cancer therapy
Iodine-131	8 days	Reactor product	Diagnosis and treatment of thyroid diseases, especially thyroid cancer
Fluorine-18	110 minutes	Accelerator product from stable, enriched oxygen-18 as the target	Most widely used PET radioisotope for detection of cancers, and treatment of neurological and cardiovascular diseases
Iridium-192	74 days	Reactor product from stable iridium-191 as target	Testing of pipeline welds, boilers, and aircraft parts
Molybdenum-99	66 hours	Reactor product	The daughter product, technetium-99m (6-hour half-life), is the most widely used isotope for diagnostic medical applications including oncology and cardiology
Palladium-103	17 days	Accelerator product from rhodium-103 as the stable target	Prostate cancer implant therapy
Strontium-89	50.5 days	Reactor product from stable strontium-88 as the target	Bone cancer pain alleviation, treatment of prostate cancer, and multiple myeloma
Thallium-201	73 hours	Accelerator product from stable isotope thallium-203 as the target	Diagnosis of coronary heart disease and heart muscle death, and location of lymphomas
Xenon-133	5.2 days	Reactor product	Pulmonary (lung) ventilation and blood flow studies

Source: Nuclear Energy Institute, *Fact Sheet: Beneficial Uses of Radiation*, Oct. 2003; Organization for Economic Cooperation and Development (OECD), Nuclear Energy Agency (NEA), *Beneficial Uses and Production of Isotopes: 2002 Update*, 13-28; and other sources.

APPENDIX C
Stable and Radioactive Isotopes: Harmonized Tariff Schedule Subheading, Description, U.S. Col. 1 Rate of Duty as of Jan. 1, 2008, U.S. Imports, 2007, and U.S. Exports, 2007

TABLE C-1. Stable and radioactive isotopes: U.S. rates of duty by Harmonized Tariff Schedule of the United States (HTS) item, U.S. domestic exports, and U.S. imports for consumption, 2007

HTS No.	Description	Col. 1 rate of duty as of Jan. 1, 2008	2007 U.S. exports	2007 U.S. imports
			Million $	
2844.40.00	Radioactive elements and isotopes and compounds other than those of uranium, plutonium, and thorium; alloys, dispersions (including cermets), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues	Free		
2844.40.00.10	Elements, isotopes and compounds with cobalt-60 radioactivity only		2.7	32.9
2844.40.00.20	Other elements, isotopes and compounds		89.8	119.9
2844.40.00.50	Other		64.4	97.8
2845	Isotopes, nonradioactive; compounds, inorganic or organic, of such isotopes, whether or not chemically defined:			
2845.10.00.00	Heavy water (Deuterium oxide)	Free	1.7	9.7
2845.90.00.00	Other	Free	40.2	41.0

Source: USITC, Harmonized Tariff Schedule of the United States 2008. Export and import data compiled from official statistics of the U.S. Department of Commerce.

APPENDIX D
Trade Data for Certain Products

TABLE D-1: Cobalt-60: U.S. domestic exports, 2003-07 (FAS value, 1,000 $)

Country	2003	2004	2005	2006	2007
Mexico	129	941	296	2,495	975
Korea	19	110	182	178	261
Germany	13	7	86	18	165
Jordan	0	4	0	50	150
Canada	72	203	57	174	113
Indonesia	75	0	0	0	103
China	25	87	796	152	101
Singapore	154	137	104	160	100
India	26	61	236	120	87
South Africa	4	4	0	104	80
Azerbaijan	0	0	0	0	79
Taiwan	110	10	14	20	66
Saudi Arabia	11	9	8	0	63
Japan	109	987	187	211	61
Venezuela	12	79	80	124	54
All other	1,025	1,064	1,335	572	284
Total	1,783	3,704	3,380	4,378	2,742

Source: Data compiled from trade data from the U.S. Department of Commerce.

TABLE D-2: Radioisotopes other than cobalt 60: U.S. domestic exports, 2003-07 (FAS value, 1,000 $)

Country	2003	2004	2005	2006	2007
Canada	19,169	20,202	21,117	20,141	30,971
Belgium	11,614	15,554	17,195	17,381	23,306
Japan	15,319	14,227	19,968	14,544	14,948
Germany	21,237	27,598	13,333	13,231	14,625
United Kingdom	13,208	7,545	12,504	11,606	10,617
Australia	3,648	4,865	4,944	6,194	5,985
Korea	2,837	3,433	4,397	4,053	4,430
Spain	5,169	5,288	5,456	6,141	4,191
China	2,622	1,746	1,782	1,729	3,531
Mexico	3,737	3,971	3,541	3,080	2,340
Taiwan	2,611	2,513	2,233	2,287	2,246
India	772	1,680	1,562	1,842	2,244
Sweden	3,382	3,389	3,174	5,639	2,214
Singapore	1,403	706	647	1,744	2,144
Brazil	1,584	2,303	1,814	1,806	2,079
All other	37,437	36,185	34,247	34,279	28,345
Total	145,747	151,204	147,916	145,696	154,216

Source: Data compiled from trade data from the U.S. Department of Commerce.

TABLE D-3: Heavy water: U.S. domestic exports, 2003-07 (FAS value, 1,000 $)

Country	2003	2004	2005	2006	2007
United Kingdom	166	173	101	225	394
Korea	0	290	70	138	338
Japan	138	50	162	123	188
Germany	88	130	249	218	175
Jamaica	0	0	0	61	93
China	0	7	14	11	92
United Arab Emirates	0	0	0	94	89
Canada	36	63	33	38	79
Kuwait	0	0	0	0	45
Trinidad & Tobago	0	0	0	0	44
Israel	0	0	0	0	36
France	6	3	13	19	31
Egypt	0	5	16	38	16
Switzerland	0	7	3	0	15
Antigua & Barbuda	0	0	0	0	14
All other	86	124	273	144	67
Total	520	853	933	1,109	1,714

Source: Data compiled from trade data from the U.S. Department of Commerce.

TABLE D-4: Stable isotopes other than heavy water: U.S. domestic exports, 2003-07 (FAS value, 1,000 $)

Country	2003	2004	2005	2006	2007
Japan	9,100	11,826	7,528	8,240	9,267
Germany	6,245	2,018	4,668	5,858	6,882
United Kingdom	1,220	1,290	1,394	2,103	5,925
France	1,944	3,249	3,612	3,737	3,208
Canada	1,644	1,432	1,532	1,945	2,365
Austria	131	70	60	40	1,637
Korea	420	596	899	746	1,400
Switzerland	2,791	1,137	1,045	1,033	1,332
China	286	712	502	1,242	1,207
Taiwan	427	463	578	370	809
Italy	698	1,268	502	763	758
Finland	56	161	357	456	602
Sweden	447	494	395	390	495
Australia	262	364	412	461	477
Netherlands	1,042	697	541	326	369
All other	1,947	2,120	3,057	4,037	3,433
Total	28,662	27,897	27,080	31,747	40,165

Source: Data compiled from trade data from the U.S. Department of Commerce.

TABLE D-5: Cobalt-60: U.S. imports for consumption, 2003-07 (Customs value, 1,000 $)

Country	2003	2004	2005	2006	2007
Canada	16,916	27,676	29,597	34,799	31,099
Russia	2,660	5,683	3,928	3,987	1,248
Germany	0	0	45	226	503
United Kingdom	2,687	12	965	500	41
South Africa	0	0	0	0	7
Belgium	0	0	2	0	0
Argentina	0	568	0	980	0
Switzerland	3	0	0	0	0
Uzbekistan	0	23	0	0	0
Thailand	0	0	6	0	0
Finland	0	0	8	0	0
France	141	0	0	0	0
Total	22,406	33,962	34,552	40,492	32,897

Source: Data have been compiled from trade data from the U.S. Department of Commerce.

TABLE D-6: Radioisotopes other than cobalt 60: U.S. imports for consumption, 2003-07 (Customs value, 1,000 $)

Country	2003	2004	2005	2006	2007
Canada	71,549	69,961	76,360	100,378	103,632
Netherlands	32,266	41,382	30,812	26,226	32,632
United Kingdom	31,316	31,391	27,818	22,191	19,615
Russia	7,570	7,763	9,918	11,894	17,979
Australia	1,944	4,429	8,136	11,749	16,810
Belgium	334	2,388	9,396	6,347	9,438
Germany	6,704	5,502	3,395	3,235	4,581
South Africa	3,407	5,472	4,567	3,158	3,602
Switzerland	2,222	2,935	2,604	2,653	3,534
Czech Republic	725	831	1,134	1,252	1,458
Uzbekistan	784	734	709	1,198	951
China	1,209	1,442	878	1,801	877
Argentina	0	0	0	0	752
Italy	86	131	253	357	437
Belarus	0	0	33	229	400
All other	3,360	4,388	2,113	1,342	956
Total	163,477	178,749	178,124	194,011	217,653

Source: Compiled from trade data from the U.S. Department of Commerce.

TABLE D-7: Heavy water: U.S. imports for consumption, 2003-07 (Customs value, 1,000 $)

Country	2003	2004	2005	2006	2007
Canada	4,821	7,561	5,634	6,987	4,846
Romania	0	696	218	3,398	3,868
India	0	0	0	0	817
Russia	0	0	8	0	77
Switzerland	0	9	0	6	54
France	27	895	39	3,331	37
Nigeria	0	0	0	0	20
Iceland	0	0	0	0	3
Japan	0	2	2	162	3
China	5	0	0	0	0
Argentina	0	156	1,022	1,379	0
Germany	15	175	3	9	0
All other	213	0	46	46	0
Total	5,080	9,494	6,973	15,317	9,724

Source: Compiled from trade data from the U.S. Department of Commerce.

TABLE D-8: Stable isotopes other than heavy water: U.S. imports for consumption, 2003-07 (Customs value, 1,000 $)

Country	2003	2004	2005	2006	2007
Georgia	1,513	637	4,945	8,842	9,486
Netherlands	6,040	5,193	3,655	6,393	9,126
Russia	13,536	12,009	10,032	9,629	6,932
Germany	4,794	3,227	2,902	2,335	5,898
Israel	8,973	6,580	5,872	4,450	3,020
Canada	3,930	1,710	1,266	2,253	2,477
China	3,751	2,947	2,920	2,818	1,956
France	1,879	1,778	827	1,305	985
Switzerland	604	861	860	1,329	817
Japan	224	217	274	150	154
United Kingdom	278	678	127	31	31
Sweden	3	67	0	7	24
India	0	0	0	0	22
Cameroon	0	0	0	0	21
New Zealand	0	0	0	0	12
All other	550	147	156	38	11
Total	46,074	35,439	33,835	39,580	40,971

Source: Compiled from trade data from the U.S. Department of Commerce.