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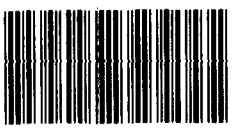
Fact Sheet for the Chairman, Environment, Energy, and Natural Resources Subcommittee, Committee on Government Operations, House of Representatives

June 1992

NUCLEAR SCIENCE

DOE's Self-Supporting Isotope Program Is Experiencing Problems



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Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-247435

June 3, 1992

The Honorable Mike Synar
Chairman, Environment, Energy, and
Natural Resources Subcommittee
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

In response to your request, we examined the status of the Department of Energy's (DOE) Isotope Production and Distribution (IP&D) Program. Specifically, we obtained information on (1) difficulties the program is having in operating on a self-supporting basis, (2) the cost factors affecting DOE's production of isotopes, and (3) domestic isotope customers' reactions to DOE's program.

Medicine, industry, and science use isotopes as powerful tools for research and in practical applications.[1] Isotope production and distribution have been a long-standing mission of DOE and its predecessor agencies. DOE supplies both radioisotopes (unstable forms of elements that emit radiation as they decay) and stable isotopes (naturally occurring, nonradioactive forms of elements). DOE's role in the isotope sales market has declined over the last 45 years. Currently, DOE generates less than 5 percent of total worldwide isotope sales. DOE reorganized its program in 1989 to centralize the management of isotope production and sales under the Office of Isotope Production and Distribution. At the direction of the Congress, IP&D was to begin operating on a totally self-supporting basis starting in fiscal year 1990.

In summary, DOE is experiencing difficulties in operating its isotope sales program on a self-supporting basis. For example, since 1990, the program's operating costs have exceeded revenues. Foreign competition and high operating costs have been the primary factors discouraging the program's self-sufficient operation. U.S. isotope users are concerned that DOE's commitment to operating the program on a self-sufficient basis may limit the domestic availability of certain isotopes if DOE cannot produce the isotopes cost-effectively.

[1]Isotopes are elements or varieties of the same chemical element, the atoms of which have the same atomic number, i.e., the same number of nuclear protons, but different atomic weights or mass (different numbers of nuclear neutrons).

Difficulties in Operating a Self-Supporting Program

DOE is experiencing difficulty operating its isotope program on a self-supporting basis. Program costs exceed revenues because the program cannot control radioisotope production costs, does not have sufficient funding to operate and maintain the equipment used to process stable isotopes,[2] faces competition in the market place, and lacks capital funds to expand and improve program operations.

The isotope program's operating fund has dropped from its initial capitalization of $16 million in 1990 to a possible insolvency by the end of fiscal year 1992. To prevent this potential insolvency, program officials, as of April 1992, were seeking immediate additional funding from within DOE. The economic consequences of having to operate on a self-supporting basis are that if the program cannot recoup its costs through isotope sales, it will have to be reduced in size or may cease to operate.

Cost Factors Affecting Isotope Production

The program's production costs vary, depending on whether the facilities producing the isotopes exist primarily for other purposes or are dedicated solely to isotope production. When the facilities exist primarily for other purposes, the isotope program pays a share of the facility's operating costs corresponding to the portion of the facility's space that it uses. For example, for producing radioisotopes, the isotope program is charged for the space that it uses in government-owned reactors and accelerators that were constructed and are used primarily for other purposes.

When facilities are dedicated exclusively to isotope production, the program is responsible for all costs, including capital expenses. For example, DOE processes stable isotopes (which represent the majority of the program's business) on dedicated equipment called calutrons. In addition, if new equipment (reactors, accelerators, or calutrons) is purchased for the production of isotopes, then the isotope program must pay for this equipment. The IP&D program is also responsible for funding the development of new isotope products. To operate on a self-supporting basis, DOE's isotope program must adjust the price of its products to ensure that all costs attributable to the program (whether capital, operating, or maintenance costs) are recovered through sales revenues.

[2]Stable isotopes are naturally occurring, nonradioactive forms of elements. They do not emit radiation or decay spontaneously; i.e., they are stable.

Domestic Isotope Customers' Reactions to DOE's Revamped Program

DOE's domestic isotope customers welcomed the centralization of DOE's program. However, they are concerned about the continued availability of certain isotopes from DOE. Because foreign suppliers offer lower prices and/or better availability, many of these customers have shifted their business to these suppliers. Domestic isotope customers are especially concerned about the possible adverse effects that the program's commitment to self-sufficiency may have on isotope availability, isotope research, and needed upgrades of isotope facilities. The isotope user community's concern about the continued domestic availability of certain isotopes has led it to request that the National Academy of Sciences study this issue. The Academy is considering starting such a study later this year.

Section 1 of this fact sheet contains additional background information on DOE's isotope program. Section 2 discusses the difficulties the program is experiencing in greater detail. Section 3 provides additional details on customers' reactions to DOE's reorganized isotope program.

Scope and Methodology

To obtain information on the IP&D program, we contacted DOE headquarters and field office officials responsible for the program. We collected data on the program for the period just before and after the reorganization through April 1992. We also contacted customers of DOE's IP&D program. These customers were suggested by DOE and the National Academy of Sciences and were from the medical, research, and commercial sectors. We did not do a financial audit of the program or a detailed review to determine whether the program has operated in a cost-effective manner.

We discussed this fact sheet with the Director and the staff of DOE's Office of Isotope Production and Distribution. They agreed with our statement of the facts. As requested, we did not obtain written agency comments on a draft of this fact sheet. Our review was conducted between June 1991 and April 1992 in accordance with generally accepted government auditing standards.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this fact sheet until 30 days from the date of this letter. At that time, we will send copies to the appropriate congressional committees; the Secretary of Energy; and the Director, Office of Management and Budget. We will also make copies available to others upon request.

If you have any questions about this fact sheet, please contact me at (202) 275-1441. Major contributors to this fact sheet are listed in appendix II.

Sincerely yours,

Victor S. Rezendes
Director, Energy Issues

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Abbreviations

DOE	Department of Energy
GAO	General Accounting Office
IP&D	Isotope Production and Distribution Program

Background Information on DOE's Isotope Program

The following summarizes background information on the activities and history of DOE's Isotope Production and Distribution (IP&D) Program.

Program Activities

DOE's annual isotope sales, which have been on the order of $15 million, represent a small percentage of the world's isotope business, estimated (in 1988) at over $500 million annually. However, DOE is considered an important supplier, since most of the isotopes that it produces are not otherwise available domestically and some have a limited worldwide backup source for their supply.

DOE produces both stable isotopes and radioisotopes. Stable isotopes are naturally occurring and are not radioactive. Radioisotopes are radioactive—i.e., they are unstable forms of elements that decay or disintegrate, emitting radiation. Radioisotopes are produced in nuclear reactors or particle accelerators and represent about 25 percent of DOE's business. (See app. I for a list of the types of radioisotopes produced.) Stable isotopes are separated in dedicated isotope separation equipment called calutrons and represent over 50 percent of DOE's business.[1] Both types of isotopes are used in many disciplines for numerous purposes—for example, in food and agriculture for food preservation and insect control, in human health for the diagnosis and treatment of disease, in industry for smoke detectors and light sources, and in basic research.

Program History

Since 1946, DOE (and its predecessor agencies) has provided isotopes to help develop and encourage the peaceful uses of atomic energy. However, from the late 1950s through the mid-1980s, DOE withdrew from producing many radioisotopes in deference to private domestic producers. DOE's share of the radioisotope market declined to the point that DOE was providing only the radioisotopes for which it had a unique production capability or for which the demand was too small to attract private producers. U.S. commercial suppliers of reactor-produced radioisotopes subsequently dropped their production of radioisotopes, and DOE resumed production of a few of these isotopes. However, today, foreign companies are the main source for most of the isotopes that DOE previously withdrew from producing.

[1]DOE's total isotopes sales (radioisotopes, stable isotopes, and related services) were about $16 million in 1990 and about $12 million in 1991. Radioisotope sales amounted to about 13 percent and 28 percent of total sales in fiscal years 1990 and 1991, respectively. Stable isotope sales represented about 80 percent and 52 percent of total sales for each of these fiscal years. The remainder of the program's sales were derived from related isotope services.

In 1981, DOE also began to withdraw from the production of stable isotopes in response to a petition from a domestic commercial supplier. This supplier, which is located within the United States, is now fully owned by the Japanese and is the sole commercial supplier of some important stable isotopes. However, DOE remains the primary domestic source of stable isotopes.

In 1989, DOE reorganized its isotope production and sales program to overcome management, organizational, and funding problems. It established the Office of Isotope Production and Distribution under the Assistant Secretary for Nuclear Energy, assuming that the objectives of the isotope program would better be served if a single group at DOE headquarters was responsible for the program. Previously, isotope program activities had taken place in several different organizational units in the DOE Offices of Energy Research, Defense Programs, and Management and Administration. The IP&D office is now solely responsible for the overall management and technical direction of DOE's isotope program, including the IP&D revolving fund, which is to be used to fund the program on a self-sustaining basis.

Before 1990, funding for isotope production and distribution originated from each of the sponsoring DOE organizations. The director of the isotope program told us that "isotope funding was provided through annual appropriations with an annual subsidy of $8 million to $12 million. Revenues received were [to be] returned to the Treasury, but in reality were retained by the Administration for use within DOE." In its fiscal year 1990 budget request, DOE, at the urging of the Office of Management and Budget, requested that an IP&D revolving fund be established to put the program on a totally self-supporting basis. The fund was approved by the Congress and came into existence at the beginning of fiscal year 1990, at which time the previous sources of funding for isotope production were stopped. The program received an initial capitalization of about $16 million from federal appropriations, which, together with isotope inventories and other assets, was expected to permit the continued production and sale of isotopes and related services on a self-sustaining basis.

Difficulties That DOE's Isotope Program Is Experiencing

The revolving fund that finances DOE's Isotope Production and Distribution (IP&D) program through revenues from sales of isotopes is being depleted because the program cannot recoup all of its costs through isotope sales. IP&D program officials acknowledge that a number of factors have limited their success in establishing a self-sustaining isotope program, including the program's inability to control and/or afford production costs, competition in the market place, and lack of capital funds to expand and improve program operations.

Status of the Isotope Program's Finances

Each year since the program became completely self-supporting, costs have exceeded revenues from the sales of isotopes. As a result, the program's revolving fund, which was capitalized with $16 million in 1990, is expected to have a balance of less than $500,000 or possibly be insolvent by the end of fiscal year 1992. Program officials said this decrease is mainly due to the cost of developing an isotope process (including the cost of cleaning up a related contamination incident), the loss of isotope sales to foreign competitors, and expenditures to maintain idle equipment (i.e., calutrons) that is used to produce stable isotopes at Oak Ridge National Laboratory. DOE's Chief Financial Officer told us in April 1992 that without immediate additional funding the program may become insolvent.

Control and Affordability of Production Costs

IP&D cannot control production costs at nondedicated production sites and cannot afford to operate and maintain dedicated production facilities.

For radioisotope production, no reactor or accelerator is currently dedicated solely to the production of radioisotopes. IP&D is merely a customer at these facilities and is charged according to the amount and location of the space used. However, IP&D is subject to charges that it cannot control. For example, the cleanup of a contamination incident related to the production and delivery of cesium sources resulted in repeated cost overruns and unplanned delays in the delivery of isotopes to customers and additional costs in excess of $2 million to the IP&D revolving fund.

Stable isotopes are processed by facilities called calutrons that are dedicated solely to the processing of these isotopes. The program cannot currently afford to operate these facilities continuously because it cannot recoup the cost of sustained operation through isotope sales. Consequently, DOE shut down the calutrons in August 1991. Nevertheless, the annual cost of maintaining the calutrons in a ready-to-restart condition

is about $2.5 million. According to the Director, the IP&D program cannot afford this cost. The program is currently using existing inventories of stable isotopes to meet customer demands (see sec. 3).

Effect of Market Competition

After more than 2 years' experience, IP&D officials have found that competition in the isotope market makes it difficult for them to establish a full cost recovery program and still sell their isotopes at competitive prices. For example, program officials said that competition from foreign suppliers contributed to an IP&D program revenue shortfall of about $4.5 million in fiscal year 1991.

The competitiveness of IP&D prices varies from isotope to isotope. For example, according to IP&D program officials, except for tritium (IP&D's largest dollar-volume isotope), DOE's prices for radioisotopes are competitive with prices for radioisotopes from non-U.S. sources. The former Soviet republics and Canada are selling tritium at one-half to two-thirds of the IP&D price. According to IP&D officials, the program has recently lost four tritium customers whose business represented 50 percent of the program's tritium sales—an annual loss of $400,000 to $500,000.

To recover costs fully, IP&D program officials raised prices for stable isotopes in mid-1990, making DOE's stable isotopes less competitive in the world market. As a result, the former Soviet republics are selling stable isotopes to U.S. customers at prices estimated to be one-half to two-thirds of current IP&D prices.

DOE also believes that its policy of withdrawing from isotope markets in favor of U.S. private enterprise has made it less competitive with foreign suppliers and not increased the availability of isotopes from domestic suppliers. Since formalizing this withdrawal policy in 1965, DOE has withdrawn at least 95 DOE isotope products. The intent was to encourage domestic private production. However, according to DOE, foreign organizations have taken over the production of most radioisotopes and many stable isotopes.

IP&D officials told us that although program pricing guidelines do not require full recovery of individual isotope costs for each fiscal year, the program cannot afford to subsidize the production costs of some isotopes with the sales revenues of others over a long period. IP&D could drop these isotopes from its inventory, but, according to program officials, the U.S.

isotope user community is exerting pressure on IP&D to continue to supply these isotopes.

Lack of Capital Funding

The IP&D revolving fund does not have capital to invest in either equipment or research. Program officials told us that unless the fund becomes highly profitable and builds a cash reserve, the program will not be able to make capital improvements, upgrades, or repairs or purchase new capital equipment. After more than 2 years' experience, program officials have concluded that the revolving fund's initial capitalization of $16 million was much too low to maintain and upgrade the isotope program.

Likewise, the IP&D program is not currently providing funds for research on new isotopes. Laboratory officials and isotope users told us that isotope research is needed to meet a growing demand for both new medical isotopes for therapy and new diagnostic isotopes. Isotope research was previously funded by the Office of Energy Research. However, since the reorganization and centralization of isotope activities, the IP&D program has been responsible for funding most isotope research. Program officials said that the revolving fund does not have the capacity to sponsor isotope research.

Pursuit of Solutions to Problems

Program officials acknowledge that, as of April 1992, the DOE isotope program is financially failing as a completely self-supporting enterprise. The program has been unable to recover all costs through isotope revenues. Program officials have made efforts to improve the prospects for self-support, including pursuing the development of revenue-producing isotopes. But they have concluded that immediate actions are required to help the program remain solvent.

Early in fiscal year 1992, officials obtained industry help and a U.S. Treasury loan to develop new revenue-producing isotopes. As part of the IP&D's program's efforts to develop new isotope product opportunities where no domestic production sources exist, IP&D program officials, in cooperation with three leading pharmaceutical companies, have agreed to study the feasibility of providing molybdenum-99 (Mo-99). Mo-99 is a radioisotope used in medical diagnostic tests—about 32,000 of which occur daily in the United States, according to DOE. The Canadians have gained a monopoly as a supplier of this isotope since the sole private U.S. source discontinued operations several years ago. (The Canadians recently lowered their price for Mo-99.) Each of the three companies provided

$40,000 as an advance against initial supply contract charges to help IP&D do a preliminary study of IP&D's ability to produce Mo-99. (One of the three companies subsequently dropped out of this agreement and is pursuing the production and sale of Mo-99 with an overseas partner.) The IP&D study, completed in August 1991, selected the Omega West Reactor at Los Alamos National Laboratory as the DOE facility to produce Mo-99. The Omega, which was previously used mainly for defense work, will now be used primarily to produce Mo-99. IP&D officials said that they hope to realize from $3 million to $5 million annually from the sale of Mo-99. Program officials expect to start selling Mo-99 during fiscal year 1993 and hope eventually to realize a profit from sales of Mo-99.

In addition, as part of its fiscal year 1992 budget, the IP&D program requested and received an $8.5-million line of credit with the Treasury to pursue new isotope initiatives, especially the Mo-99 initiative. IP&D officials believe that they may need to borrow more in the future to help overcome the difficulties arising from what they view as an initial undercapitalization of the revolving fund and permit them to seize new product opportunities when they are identified.

Program officials told us in April 1992 that the benefits of efforts such as the Mo-99 initiative may accrue too late to keep the program solvent. They said that they are pursuing more immediate solutions to the program's funding problems, including seeking additional funds from within DOE. They also plan to engage a management consulting firm in the near future to help identify longer-term solutions to the program's problems. In addition, representatives of the Inspector General's Office told us that the Department's Chief Financial Officer may request that their office assess the management and financial status of the program's revolving fund.

Customers' Reactions to DOE's Reorganized Isotope Program

The following discusses some customers' reactions to DOE's current Isotope Production and Distribution program and concerns about the availability of isotopes from DOE. It also discusses a proposed study by the National Academy of Sciences of isotope availability.

Customers' Reactions and Concerns

Some of DOE's customers view the reorganization of DOE's isotope program favorably because it has provided a central point of contact for the program. However, some customers told us that although price is important, concerns about the reliability and availability of isotopes from DOE are the primary reason that they purchase isotopes from foreign suppliers.

Some of DOE's customers were especially concerned about decreases in DOE's inventories of stable isotopes. IP&D program officials told us that inventories are sufficient to meet current demand. However, these officials acknowledged that they are not presently replenishing inventories because the calutrons that produce the stable isotopes are expensive to run continuously. Program officials told us that they are discussing the possibility of long-term contracts with major pharmaceutical companies to pay for the continuous operation of the calutrons.

Some customers, as well as DOE laboratories, are also concerned that the IP&D program does not have enough funding to develop new isotopes (a traditional role for DOE), especially the isotopes needed for medical diagnostic and therapeutic purposes. Some users noted that the reorganization minimized isotope research by virtually eliminating funding for new isotope development by DOE laboratories.

Possible National Academy of Sciences Study of Isotope Availability

Because of concerns voiced by the scientific community, the National Academy of Sciences is considering a study of the problems associated with the domestic availability of isotopes, especially for research and biomedical applications. If the Academy decides to study this issue, the study might start later in 1992 and take about a year to complete.

The Academy said that the need for a reliable source of isotopes in the United States is of considerable concern to a broad cross section of the scientific community. The Academy pointed out that the needs of various users differ greatly. For example, basic researchers require small amounts of many different stable isotopes, whereas the commercial sector needs large quantities of more limited numbers of isotopes. The Academy said

that it is not clear whether domestic suppliers are currently meeting the different needs of the various users.

DOE isotope program officials told us that the results of the proposed study by the Academy may come too late to be of help to DOE. In addition, the officials stated that they would prefer to do their own study, which would specifically concentrate on improvements to be made to their program.

Radioisotopes Produced by DOE

Radioisotope	Site	Facility	Use[a]
Aluminum-26 (Al)	Los Alamos Nat'l Lab	Linear accelerator	R
Americium-241 (Am)	Los Alamos Nat'l Lab	From inventory	C
Arsenic-72/73/74 (As)	Los Alamos Nat'l Lab	Linear accelerator	R
Beryllium-7 (Be)	Brookhaven Nat'l Lab	Linear accelerator	M
	Los Alamos Nat'l Lab	Linear accelerator	M
Bismuth-207 (Bi)	Los Alamos Nat'l Lab	Linear accelerator	R
Cadmium-109 (Cd)	Los Alamos Nat'l Lab	Linear accelerator	R
Californium-252 (Cf)	Oak Ridge Nat'l Lab	High Flux Isotope Reactor	C, M
Cesium-137 (Cs)	Westinghouse Hanford Co.	From inventory	C, M
Cobalt-60 (Co)	Idaho Nat'l Eng. Lab	Advanced Test Reactor	C, M
Copper-67 (Cu)	Brookhaven Nat'l Lab	Linear accelerator	M
	Los Alamos Nat'l Lab	Linear accelerator	M
Gadolinium-153 (Gd)	Westinghouse Hanford Co.	Fast Flux Test Facility	M
	Idaho Nat'l Eng. Lab	Advanced Test Reactor	M
Germanium-68 (Ge)	Los Alamos Nat'l Lab	Linear accelerator	C, M
	Brookhaven Nat'l Lab	Linear accelerator	C, M
Hafnium-172 (Hf)	Los Alamos Nat'l Lab	Linear accelerator	R
Iridium-192 (Ir)	Idaho Nat'l Eng. Lab	Advanced Test Reactor	C, M
	Oak Ridge Nat'l Lab	High Flux Isotope Reactor	C, M
Iron-52 (Fe)	Brookhaven Nat'l Lab	Linear accelerator	M
Iron-55 (Fe)	Los Alamos Nat'l Lab	Linear accelerator	R
Krypton-85 (Kr)	Idaho Nat'l Eng. Lab	Fuel processing	C
	Oak Ridge Nat'l Lab	From inventory	C
Magnesium-28 (Mg)	Brookhaven Nat'l Lab	Linear accelerator	M
Neptunium-237 (Np)	Oak Ridge Nat'l Lab	From inventory	R
Nickel-63 (Ni)	Idaho Nat'l Eng. Lab	Advanced Test Reactor	C
Palladium-103 (Pd)	Oak Ridge Nat'l Lab	High Flux Isotope Reactor	M
Plutonium-238/239/240/241 (Pu)	Oak Ridge Nat'l Lab	From inventory	R
Radium-224 (Ra) and daughters	Argonne Nat'l Lab	Thorium-228 generator	M
Rubidium-83 (Rd)	Los Alamos Nat'l Lab	Linear accelerator	M
Ruthenium-97 (Ru)	Brookhaven Nat'l Lab	Linear accelerator	M
Selenium-72 (Se)	Los Alamos Nat'l Lab	Linear accelerator	R
Selenium-75 (Se)	Los Alamos Nat'l Lab	Linear accelerator	M, R
Silicon-32 (Si)	Los Alamos Nat'l Lab	Linear accelerator	R

(continued)

Radioisotope	Site	Facility	Use[a]
Sodium-22 (Na)	Los Alamos Nat'l Lab	Linear accelerator	M
Strontium-82 (Sr)	Brookhaven Nat'l Lab	Linear accelerator	M
	Los Alamos Nat'l Lab	Linear accelerator	M
Strontium-85 (Sr)	Los Alamos Nat'l Lab	Linear accelerator	C
Strontium-90 (Sr)	Westinghouse Hanford Co.	From inventory	C
Technetium-96 (Tc)	Brookhaven Nat'l Lab	Linear accelerator	R
Technetium-99 (Tc)	Oak Ridge Nat'l Lab	From inventory	R
Titanium-44 (Ti)	Los Alamos Nat'l Lab	Linear accelerator	R
Tritium (H-3)	EG&G Mound Lab	Chemical laboratory	C
Uranium-233/234/235/ (U)	Oak Ridge Nat'l Lab	From inventory	C, R
Uranium-236 (U)	Oak Ridge Nat'l Lab	From inventory	R
Vanadium-48/49 (V)	Los Alamos Nat'l Lab	Linear accelerator	R
Xenon-127 (Xe)	Brookhaven Nat'l Lab	Linear accelerator	M
Yttrium-88 (Y)	Los Alamos Nat'l Lab	Linear accelerator	M
Yttrium-90 (Y)	Argonne Nat'l Lab	Strontium-90 generator	M
	Westinghouse Hanford Co.	Fast Flux Test Facility	M
Zinc-65 (Zn)	Los Alamos Nat'l Lab	Linear accelerator	M

[a]C = Commercial
M = Medicine
R = Research

Source: Prepared by GAO from data furnished by DOE.

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