

Background

The Department of Energy's Isotope Programs produces and sells many stable and radioactive isotopes that are widely used by domestic and international customers for medicine, industry, and research. DOE provides isotopes only when there is no U.S. private sector capability or when the available supply is insufficient to meet U.S. needs. The Department encourages private sector investment in new isotope production ventures and will sell or lease its existing facilities and inventories for commercial purposes.

The Isotope Programs operates with a revolving fund and maintains financial viability for processing isotopes through revenues from sales. Starting in FY 2003, all isotopes will be sold to recover production cost. In FY 2001, the Isotope Programs served a total of over 300 customers, generating revenues of \$7.9 million. The total number of deliveries made were 591, of which over 94 percent of these orders were delivered to customers on schedule.

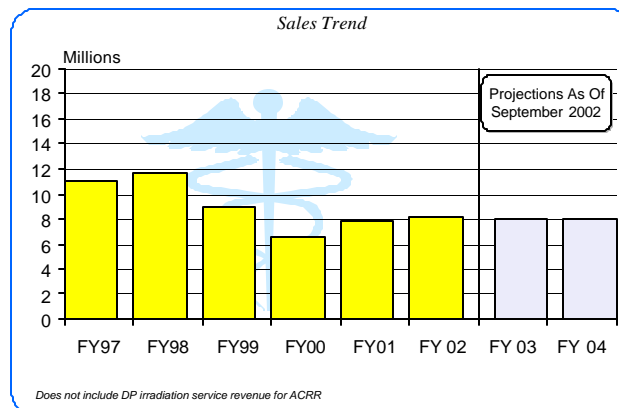
Isotopes for Life

As the range of available isotopes and the recognized uses for them have increased, new or improved isotope products have become essential for progress in medical research and practice, new industrial processes, and scientific methodology. Also, a substantial national and international infrastructure has been built around the use of isotopes. For example, thallium-201 is used for medical cardiac imaging and calcium-44 is used in bone growth studies. Iridium-192 is used for nondestructive testing of construction and other materials and americium-241 is used in smoke detectors.

Promising new isotopes for medical applications include rhenium-188, a beta-emitting isotope that is showing great promise for treatment of cancer, relief of bone pain, and prevention of coronary restenosis. Demand for this isotope is expected to increase substantially in the next year. Tungsten-188 is manufactured in a reactor at Oak Ridge National Laboratory and packaged there into tungsten/rhenium generators that are shipped to research and clinical users all over the world.

Iodine-125 is an important isotope in the treatment of prostate cancer. A reactor at Sandia National Laboratories, New Mexico, has been used to produce iodine-125. However, the Department has reached an agreement with the McClellan Nuclear Radiation Center at the University of California, Davis that has enabled them to take over iodine-125 production from the Department using the Department's unique production technology.

As a new area of concentration, the Advanced Nuclear Medicine Initiative was implemented in FY 2000. This initiative supports peer-reviewed research to further advance nuclear medicine technology in the United States. The first



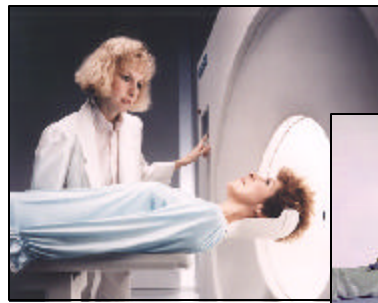
solicitation of applications under the Advanced Nuclear Medicine Initiative was made in FY 2000. Nine research grants were made in September, 2000 to the Garden State Cancer Center, Oak Ridge National Laboratory, Regents of the University of Michigan, University of Chicago, University of California Davis, University of Washington, Westinghouse Electric Company LLC, and two awards to the Curators of the University of Missouri. The five educational grants to support nuclear medicine disciplines at universities and colleges were made in March 2001 to Washington University, Purdue University, University of New Mexico Health Sciences, Regents of the University of Wisconsin System, and Washington State University.

The Advanced Nuclear Medicine Initiative program was initiated with FY 2000 funds. Each grant was awarded for a period of three years. Due to a change in focus to emphasize other research and development activities such as near-term deployment of new nuclear plants, no new funds were requested for the program in FY 2003. However, research initiated in FY 2000 will be concluded in FY 2003 using FY 2002 funds.

Another key initiative of the Isotope Programs is the processing and extraction of alpha-emitting isotopes from residual uranium materials stored at the Oak Ridge National Laboratory. Researchers throughout the United States are assessing alpha-emitting radioisotopes that can destroy cancer cells and reduce tumors. Alpha-emitters such as Bismuth-213 have been demonstrated to be successful for cancer therapy. In an effort to meet increased demand to support human clinical trials, the Department expanded its processing to achieve a 30 percent increase in supply over FY 2001. Beginning in FY 2003, any future processing of thorium-229 will be financed by the private sector.

For the long term, the Department plans to double the supply of Bismuth-213. A Notice of Program Interest to investigate accelerator and reactor concepts for the large-scale production of Ac-225/Bi-213 generators resulted in the submission of six proposals. After review by a peer review

panel, two submissions were selected for awards. The two awards were made to AlphaMed Corporation and the University of Missouri on September 14, 2001. The results of these awards should provide the basis for development of large-scale production to meet future demand for this promising therapeutic agent. These agreements will end in FY 2002.



Isotopes Are Used For Diagnostic Imaging



Nuclear Energy Protocol for Research Isotopes. Starting in FY 2002 with full implementation in FY 2003, the Department will apply a more formal,

peer-review structure to the process it applies to the production and distribution of research isotopes. This new process is called the Nuclear Energy Protocol for Research Isotopes. Under this protocol, a peer-reviewed process will be applied to determine which isotopes will be eligible for production by the Department

An additional FY 2002 effort secured a cooperative arrangement with MedActinium for the production of radium-224 (a daughter of U-232). Radium-224 is the parent of Bi-212, another alpha-emitting radioisotope showing promise for cancer therapy. It is anticipated that in FY 2003 a Ra-224 production facility will be established at Pacific Northwest National Laboratory that will provide quantities of Ra-224 suitable for both ongoing research and future clinical trials.

Program Highlights for Fiscal Year 2003

The Isotope Programs' FY 2003 budget includes, in addition to support for continuing operations at four production sites, several major initiatives: the restructuring of the program's financial basis, the Nuclear Energy Protocol for Research Isotopes, and the new Isotope Production Facility.

Program Financial Restructuring. The Department will continue to make new capital investments to replace, or enhance processing equipment and infrastructure in order to improve production and processing of isotopes to meet current and anticipated future increases in demand. Beginning in FY 2003, the facilities and infrastructure activities previously funded in the Isotope Programs have been consolidated into one account, the Radiological Facilities Management program. This will more accurately reflect the activities being performed at NE managed sites and facilities. The Radiological Facilities Management program includes maintaining DOE NE facilities in a user-ready status to support vital DOE missions at Brookhaven, Los Alamos, Oak Ridge and Sandia National Laboratories.

in a given year. The Department will apply an open, public process to determine and announce each year which research isotopes it will produce. Once a list of isotopes has been selected for production, customers must provide the Department advance cash payment to cover production costs. Each isotope will be priced such that its cost of production is paid by the customer for that isotope. No isotope program funds will be expended on the development or production of these isotopes.

New Facility at Los Alamos National Laboratory.

Construction of the Los Alamos Isotope Production Facility has been completed. Commissioning and startup activities, begun in FY 2002, will enable isotope production of short-lived medical and scientific isotopes to begin in FY 2004.

Summary

Research into the use of isotopes for medical, industrial, environmental, and other important applications shows great promise to improve the quality of life for the citizens of the United States and the world. Growth in these very beneficial and cost-effective applications can only occur if the infrastructure for reliable production of isotopes is maintained and isotopes are made available to researchers. Through its Isotope Programs, the Department of Energy is committed to continue its support of this very valuable research.

Program Budget Isotope Programs ¹ (\$ in Millions)			
	FY 2001 <u>Approp.</u>	FY 2002 <u>Approp.</u>	FY 2003 <u>Request</u>
Isotope Programs' Operations	\$ 13.7	\$ 12.2	\$ 12.1
Isotope Production Facility Construction	3.0	2.5	1.7
Advanced Nuclear Medicine Initiative	<u>2.5</u>	<u>2.5</u>	<u>0.0</u>
TOTAL	\$ 19.2	\$ 17.2	\$ 13.8

¹Funds included in the Radiological Facilities Management Program

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