Isotope Production and Distribution Program Fund

Program Overview

The Department of Energy's Isotope Program produces and sells radioactive and stable isotopes, byproducts, surplus materials, and related isotope services world-wide, and operates under a revolving fund established by the 1990 Energy and Water Appropriations Act (Public Law 101–101), as modified by Public Law 103–316. The combination of an annual direct appropriation and cash collections/ advance payments from isotope sales are deposited in the Isotope Production and Distribution Program Fund, the revolving fund. This revolving fund allows continuous and smooth operations of isotope production, sales, and distribution independent of the federal budget cycle. The fund's revenues and expenses are audited annually consistent with Government Auditing Standards and other relevant laws, such as the Chief Financial Officers Act of 1990 and the Government Performance and Results Act of 1993.

The Program's fiscal year appropriation is received via transfer from the Office of Science's Nuclear Physics program (see the Isotope Development and Production for Research and Applications section of the Nuclear Physics program within the Office of Science appropriation). Appropriated funds are used to support the scientists and engineers needed to carry out the Isotope Program and to operate and maintain isotope facilities to assure reliable production. In addition, the appropriation provides support for R&D activities associated with the development of new production and processing techniques for isotopes, operations support for the production of research isotopes, and support for the training of new personnel in isotope production and development. Each of the sites' production expenses for processing and distributing isotopes is offset by revenue generated from sales. The combination of appropriated funds and revenue from sales maintain the financial viability of the program. Of the total resources available annually in the revolving fund, about 75 percent is used for operations, maintenance, and isotope production, with roughly 25 percent available for process improvements, unanticipated changes in volume, and purchases of small capital equipment, such as assay equipment and shipping containers needed to ensure on-time deliveries.

Isotopes are primarily produced and processed at three facilities, which are stewarded by the Isotope Program: the Isotope Production Facility at Los Alamos National Laboratory, the Brookhaven Linac Isotope Producer at Brookhaven National Laboratory, and processing facilities at Oak Ridge National Laboratory (ORNL). In addition, the Isotope Program is planning to use the hydraulic tube at the Advanced Test Reactor at the Idaho National Laboratory for radioisotope production. This upgrade will provide additional capability to produce short-lived medical and scientific research isotopes in short supply. At the Pacific Northwest National Laboratory (PNNL), the Isotope Program will continue to distribute strontium-90, a byproduct material of the past weapons programs, and is reviewing the possibility of processing other byproduct material stored at PNNL. Additional capability is provided by the High Flux Isotope Reactor, which is presently producing californium-252 for the Isotope Program. The Isotope Program is increasing productivity by broadening the suite of production facilities to include university accelerator and reactor facilities and other Federal agency facilities which can provide

cost-effective and unique production capabilities; these include the Washington University, the University of California at Davis, and the Missouri University Research Reactor.

Background

The Department has supplied isotopes and related services for more than 50 years. These isotope products and services are used by medical institutions, universities, research organizations, and industry for a wide array of purposes. Isotopes are also provided to many Federal agencies, either directly or indirectly, including the National Institutes of Health and its grantees, the Environmental Protection Agency, and the Department of Homeland Security.

As the range of available isotopes and the recognized uses for them increased, new or improved isotope products contributed to progress in medical research and treatment, new industrial processes, and scientific investigation. Substantial national and international scientific, medical, and research infrastructure has relied upon the use of isotopes and is strongly dependent on the Department's products and services. Isotopes are now used for hundreds of research, biomedical, homeland security, and industrial applications that benefit society every day such as heart imaging, cancer therapy, smoke detectors, neutron detectors, explosives detection, oil exploration, and tracers for climate related research.

Isotope applications are widely used in medical research, diagnosis, and therapies, which are a growing component of the U.S. health care system. It is estimated that the treatment of one in every three people at a hospital makes use of a radioisotope in laboratory tests, diagnoses, or therapy. Each day, over 40,000 medical patients receive nuclear medicine procedures in the United States. Such nuclear procedures are among the safest diagnostic tests available. They enhance patient care by avoiding exploratory surgery and similar procedures. For example, it has been demonstrated that the use of myocardial perfusion imaging in emergency room chest pain centers can reduce the duration of stay on average from 46 hours to 12 hours. Adequate supplies of medical and research isotopes are essential to the Nation's health care system and to basic research and industrial applications that contribute to national economic competitiveness.

Isotope uses in homeland security applications are also increasing and include radiation portal monitors used to find unshielded or lightly shielded radiological material, imaging systems used to find densely shielded material, systems to detect the presence of nitrogen-based chemical explosives, and other forms of explosives detection.

The total budgetary resources available in the revolving fund in FY 2010 were $37.8 million. This consisted of $19.1 million from the FY 2010 direct Nuclear Physics appropriation, and collections of $18.7 million, which were used to cover expenses, support research into alternative production and processing techniques, and develop new production capabilities. Collections increase or decrease depending on customer demand, production efficiencies, and the availability of facilities. The collections in FY 2010 represent a decrease relative to FY 2009 due to large advance payments made in FY 2009 for californium-252. However, compared to recent years, sales and production of californium-252, selenium-75, and strontium-82 continue to increase. Californium-252 has a variety of industrial and medical applications, selenium-75 is used as a radiography source, and strontium-82 has gained world-

wide acceptance for use in heart imaging which has resulted in increased sales over the last several years. Effective management of the Isotope Program requires constant diligence as factors which influence the program are dynamic by their nature. For example, sales are not static; they can fluctuate on a monthly basis, presenting a challenge for managing a productive and optimized staff involved in commercial isotope production.

In FY 2010, the Isotope Program served over 140 customers including major pharmaceutical companies, industrial users, and over 100 researchers at hospitals, national laboratories, universities, and private companies. There are about ten high-volume and moderately priced isotopes among the many produced by the Program; the remaining isotopes are low-volume research isotopes and thus more expensive to produce. Progress has been made in the past year in evaluating the pricing of isotopes in an effort to make research isotopes more affordable; these efforts are continuing. Commercial isotopes will continue to be priced to recover full cost. Research isotopes will be provided at a reduced price that will provide compensation to the government while encouraging research and development. For example, some expenses that were paid traditionally by the researcher are now being supported with appropriated funds, reducing the price of the research isotope to the customer. Improved communication with the user community and federal agencies has improved the ability to forecast demand of needed isotopes, which positions the Isotope Program to better meet the projected needs of the community, resulting in a more reliable supply of research isotopes.

Of the isotopes produced by the Isotope Program, the majority are for medical research. Over 420 shipments were made in FY 2010. Roughly a third of these shipments were to foreign countries with the remainder sold domestically, including 10% or less to other Federal agencies. Customer satisfaction with product specifications has traditionally been very high with over 98% of products and services provided meeting the terms of the contract/sales order in FY 2010.

Selected FY 2010 Accomplishments

- The demand for californium-252 continues to grow. A fourth sealed source manufacturer has met the requirements and has been added to the californium-252 contract arrangement with the three original industrial partners. Californium-252 is used for nuclear reactor start-up sources, mining and cement manufacturing, nuclear fuel interrogation, medicine, research, and homeland and national security. This isotope is only produced in the U.S. and Russia.
- Selenium-75 production increased about 30% over FY 2009 due to a new target design that permits a larger number of customer-provided capsules to be irradiated in the HFIR at ORNL. Selenium-75 is used for gamma radiography and is an alternative to iridium-192 for some applications.
- Stronium-82, used in heart imaging, continues to have significant worldwide growth in usage. For example, in FY 2010, the Isotope Program produced and shipped over 82,000 millicuries of this commercial medical isotope, which was a 303% increase over FY 2005. Demand continues to grow in FY 2011 for this Positron Emission Tomography (PET) imaging isotope, partly because it is an alternative for some of the molybdenum-99/technetium-99m modalities.

Budget Overview

For FY 2012 and the future, the Department foresees more than moderate growth in isotope demand, coupled with the possible need for new isotope products for homeland security, medicine, and industry. In order to satisfy the needs of its customers, the program seeks to meet supply requirements for year-round availability of isotopes for scientific and medical research and, in particular, for human clinical trials. The program's production capability may be called upon for initial ramp-up of production of major new isotope products until market forces bring in private producers that are willing to invest and produce the needed isotopes.