Isotope Production and Distribution Program Fund

Overview

The Department of Energy's (DOE) Isotope Production and Distribution Program Fund, more commonly called the DOE Isotope Program (DOE IP), provides critical isotopes in short supply to the Nation to ensure robust domestic supply chains to meet federal missions, facilitate emerging technology, reduce U.S. dependence on foreign supply, and promote the Nation's economic prosperity and technical strength. The DOE IP produces and sells radioactive and stable isotopes, byproducts, surplus materials, and related isotope services worldwide, and is often the single source for these critical assets. Isotopes are used for hundreds of essential applications that benefit society every day, such as revolutionary new cancer therapy, diagnostic medical imaging, environmental studies, smoke detectors, explosives detection, quantum computing, advanced manufacturing, nuclear batteries, space exploration, clean energy and biological tracers. For example, radioisotopes are used in the diagnosis or treatment of about one-third of all patients admitted to hospitals.[a] Substantial national and international research, medicine, industry, and national security relies upon the use of isotopes and is strongly dependent on the Department's products and services.

A priority of the Program is to mitigate the Nation's dependency on foreign supply chains of isotopes, particularly those from sensitive countries, that are essential for facilitating emerging technology. DOE IP continuously assesses isotope needs to inform program direction, including biennial federal workshops to evaluate U.S. federal demand, in order to optimize the utilization of resources and assure the greatest availability of isotopes for the advancement of federal missions and emerging technology.

The Department supplies isotopes and related services to the Nation under the authority of the Atomic Energy Act of 1954, which specifies the role of the U.S. Government in isotope distribution. Isotopes sold to commercial customers are priced to recover the full cost of production or the market price (whichever is higher). Research isotopes are sold at a reduced price to ensure that the high priority research requiring them does not become cost prohibitive. The Program operates under a revolving fund, the Isotope Production and Distribution Program Fund, established by the 1990 Energy and Water Development Appropriations Act (Public Law 101-101), as amended by the 1995 Energy and Water Development Appropriations Act (Public Law 103-316). Funding for this revolving fund is provided by the combination of annual appropriations from the Science appropriation account (from the new Office of Isotope R&D and Production Program (IRP)) beginning in FY 2022; prior to FY 2022 appropriations were included in the Nuclear Physics program), and collections from isotope sales; both are needed to maintain the Isotope Program's viability. The revolving fund allows continuous and smooth operations of isotope production, sales, and distribution independent of the federal budget cycle and fluctuating sales revenue. An independent cost review of the fund's revenues and expenses is conducted annually by an external contractor.

Annual appropriations in IRP fund a payment into the revolving fund to maintain mission-readiness of facilities, including the support of core scientists and engineers needed to produce and process isotopes, and the maintenance and enhancement of isotope facilities and capabilities to assure reliable production and provide novel isotopes in high demand and short supply. In addition, appropriated funds provide support for R&D activities associated with development of new production and processing techniques for isotopes and workforce development in isotope production and chemical processing. Each site's production expenses, including processing and distributing isotopes, are offset by revenue generated from sales. About 80 percent of the resources in the revolving fund are used for operations, maintenance, isotope production, and R&D for new isotope production techniques, with approximately 20 percent available for process improvements, unanticipated changes in revenue, manufacturing equipment, capability and infrastructure upgrades, and capital equipment such as assay equipment, glove boxes, and shipping containers needed to ensure on-time deliveries.

The DOE IP produces radioisotopes by irradiating targets in accelerators and reactors at national laboratories and universities, and from extraction of materials and legacy waste. Accelerator facilities include the Brookhaven Linac Isotope Producer at Brookhaven National Laboratory, the Isotope Production Facility at Los Alamos National Laboratory, the Low Energy Accelerator Facility at Argonne National Laboratory, and the University of Washington cyclotron. Reactor facilities

[a] https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/med-use-radioactive-materials.html

include the Advanced Test Reactor at Idaho National Laboratory, the High Flux Isotope Reactor at Oak Ridge National Laboratory (ORNL), and the University of Missouri Research Reactor. Irradiated targets are processed in associated hot cells and gloveboxes at these facilities. Isotopes are extracted and purified at the Y-12 National Security Complex near ORNL, processing facilities at the Pacific Northwest National Laboratory, and the Savannah River Site. Enriched stable isotopes are produced at the Enriched Stable Isotope Prototype Plant at ORNL.

In FY 2020, a total of $117.2 million was deposited into the revolving fund. This consists of the FY 2020 appropriation of $62.3 million paid into the revolving fund from the Nuclear Physics (NP) program, plus collections of $54.9 million to recover costs related to isotope production and isotope services. In FY 2020, the DOE IP sold over 120 different radioactive and stable isotopes to a broad range of research and commercial customers, including major pharmaceutical companies, industrial stakeholders, and researchers at hospitals, national laboratories, other federal agencies, universities, and private companies. Among the isotopes produced, about ten are high-volume isotopes often with commercial applications and the remaining are low-volume, mostly research isotopes, which are more expensive to produce and thus not readily available.

Collections in FY 2020 included, for example, sales of actinium-225, actinium-227, strontium-89, californium-252, helium-3, nickel-63, and selenium-75. The DOE IP is the global leader in the development and provision of alpha-emitters for novel cancer-fighting therapies, enabling and accelerating the conduct of clinical trials. Actinium-225 is used in pharmaceuticals under development to treat cancer and other diseases more effectively. Actinium-227 provides radium-223 for Xofigo®, which is the first alpha particle-emitting radioisotopic drug approved by the Federal Drug Administration; Xofigo® extends patient survival as well as alleviates the excruciating pain associated with cancer that has metastasized to bone. Californium-252 has a variety of industrial applications, including oil and gas well-logging and fission start-up sources in nuclear reactors. Helium-3 is used in neutron detectors for national security and cryogenics. Nickel-63 enhances national security through its use in detectors for explosives and illicit material, and also enhances performance of nuclear batteries. Selenium-75 is used as a radiography source.

Highlights of the FY 2022 Request

For FY 2022, the Department foresees continued strong growth in isotope demand, including alpha and beta emitters for novel cancer therapy and medical diagnostics; stable isotopes to enable high-discovery science, emerging technologies in medicine and national security; isotopes for quantum information science; isotopes to promote clean energy; and isotopes for batteries and power supplies. The FY 2022 Request of the IRP Budget is $90.0 million. Revolving fund resources will be used to address the following priorities in the program:

- Maintain and enhance critical infrastructure and core competencies for isotope production to address unanticipated gaps and lack of capabilities in international supply chains for high priority and new isotopes
- Through cutting-edge research and advanced manufacturing, introduce novel isotopes to the Nation to facilitate emerging technology and applications (medicine, quantum computing, clean energy, nuclear batteries…), promoting U.S. economic prosperity and technical strengths
- Mitigate U.S. dependence on foreign supply chains and promote domestic production capabilities with technology transfer
- Enhance isotope processing capabilities to address a lack of infrastructure limiting the availability of new isotopes and mitigating single point failures to increase the Nation’s preparedness for reacting to global supply chain disruptions
- Advance and expand stable isotope enrichment capabilities

The FY 2022 Request in the IRP Budget includes $3.2 million to continue the Isotope Harvesting research effort at the Facility for Rare Isotope Beams (FRIB) to add the capabilities to extract and process significant quantities of high-value isotopes from the FRIB beamdump. FRIB, funded in the Nuclear Physics program, is a DOE Scientific User Facility dedicated to the study of nuclear structure and astrophysics research. The FY 2022 Request in the IRP also includes $12.0 million to continue the U.S. Stable Isotope Production and Research Center (SIPRC) at ORNL, to significantly enhance stable isotope production capacity for the Nation. This Line Item Construction Project will build upon the expertise in centrifuge and electromagnetic isotope separation technology nurtured by the Stable Isotope Production Facility (SIPF) Major Item of

Equipment, funded through NP and IRP, which receives pre-operations support in FY 2022. The IRP Request supports and participates in a number of high priority initiatives for the Department and Administration, including Advanced Manufacturing, National Preparedness in the Biopreparedness Research Virtual Environment (BRaVE) initiative, Quantum Information Science, Artificial Intelligence and Machine Learning, Climate/Clean Energy, and the Reaching a New Energy Sciences Workforce (RENEW) initiative.

Program Accomplishments

DOE Isotope Program Maintains Operations During COVID-19 Pandemic

As a Mission Essential Function in the DOE, the DOE IP continued isotope production operations throughout the COVID-19 pandemic in FY 2020 which ensured supply chain robustness in critical isotopes. The production sites across the national laboratory complex quickly and successfully established safe protocols for continued operations to ensure critical isotope supply, and overcame extraordinary global transportation hurdles. Not only did the Program meet commitments to its stakeholders during the pandemic, but the Program monitored international supply chains and stepped in to fill shortages when international suppliers could either not produce or transport their product during the pandemic. In FY 2020, DOE IP made 359 shipments of isotopes during the pandemic.

DOE IP Provided Californium-252 for a Startup Source to First New Nuclear Reactor in U.S. in 30 Years

Californium-252 produced at the ORNL High Flux Isotope Reactor has been produced and specially formed into wires for use as sources to start operations of two new nuclear reactors in Georgia—Plant Vogtle Units 3 and 4, creating the largest nuclear power station in the U.S. These will be the first new nuclear units built in the U.S. in the last three decades. Californium-252 is only produced in the U.S. and Russia, and is required to startup such nuclear reactors enabling a stable supply of electrical energy to U.S. society.

Establishment of Domestic Enrichment of Ytterbium-176 for Use in Radiopharmaceutical Production

There is a global shortage of ytterbium-176, which is highly sought after as feedstock for lutetium-177 production, used worldwide in radiopharmaceuticals for the targeted treatment of gastrointestinal tumors and metastatic prostate cancer. Production of highly enriched ytterbium-176, which until now has only been produced in Russia, was demonstrated at ORNL in the Enriched Stable Isotope Prototype Plant. R&D activities in ion source technology, ion beam optics, and collection systems at ORNL culminated in the production of several batches of highly enriched ytterbium-176. Efforts are underway to expand production capabilities.