## Isotope Production and Distribution Program Fund

### Overview

The Department of Energy's Isotope Program (DOE IP) produces and sells radioactive and stable isotopes, byproducts, surplus materials, and related isotope services worldwide. It 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 the Isotope Production and Distribution Program Fund is provided by the combination of annual appropriations from the Isotope Development and Production for Research and Applications subprogram within the Nuclear Physics (NP) program in the Science appropriation account, and collections from isotope sales; both are needed to maintain the Isotope Program's viability. This 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 NP funds a payment into the revolving fund to maintain mission-readiness of facilities, including the support of core scientists and engineers needed to carry out the Isotope Program and the maintenance of isotope facilities to assure reliable production. In addition, appropriated funds provide support for research and development (R&D) activities associated with development of new production and processing techniques for isotopes, production of research isotopes, and training of new personnel in isotope production. 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 volume, and purchases of small capital equipment, such as assay equipment and shipping containers needed to ensure on-time deliveries.

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. Substantial national and international scientific, medical, and research infrastructure relies upon the use of isotopes and is strongly dependent on the Department's products and services. Isotopes are used for hundreds of applications that benefit society every day, such as diagnostic medical imaging, cancer therapy, smoke detectors, neutron detectors for homeland security applications, explosives detection, oil exploration, and tracers for environmental research. For example, radioisotopes are used in the diagnosis or treatment of about one-third of all patients admitted to hospitals.[a] More than 20 million Americans benefit each year from nuclear medicine procedures used to diagnose and treat a wide variety of diseases.[b] Such nuclear medicine procedures are among the safest and most effective diagnostic tests available and enhance patient care by avoiding exploratory surgery and other invasive procedures. DOE IP continuously assesses isotope needs to inform program direction including biennial Federal workshops to evaluate stakeholder requirements in order to optimize the utilization of resources and assure the greatest availability of isotopes.

Radioisotopes are primarily produced and processed at three facilities stewarded by DOE IP: the Brookhaven Linac Isotope Producer (BLIP) and associated processing labs at Brookhaven National Laboratory (BNL), the Isotope Production Facility (IPF) and associated processing labs at Los Alamos National Laboratory (LANL), and the processing labs at Oak Ridge National Laboratory (ORNL). Enriched stable isotopes are produced at the Enriched Stable Isotope Prototype Plant (ESIPP) also at ORNL. In addition, production and distribution activities are supported at the Advanced Test Reactor (ATR) at Idaho National Laboratory (INL), the High Flux Isotope Reactor (HFIR) at ORNL, the Y-12 National Security Complex near ORNL, the Low Energy Accelerator Facility (LEAF) at Argonne National Laboratory (ANL), and processing facilities at the Pacific Northwest National Laboratory (PNNL) and the Savannah River Site. IPF, BLIP, and LEAF provide accelerator production capabilities, while HFIR and ATR provide reactor production capability. HFIR has the highest neutron flux available for isotope production in the United States. ESIPP represents the re-establishment of general enriched stable isotope production capabilities in the U.S. and started operations in 2016. DOE IP is further broadening capability by including university-supported accelerator and reactor facilities used for research, education, and isotope production that can

[a] https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/med-use-radioactive-materials.html
[b] http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=4825

provide cost-effective and unique production capabilities, as the University of Washington and the Missouri University Research Reactor are now part of the DOE IP University Production Network. Many other universities have expressed interest in participating in the network.

In FY 2019, a total of $102,421,821 was deposited into the revolving fund. This consisted of the FY 2019 appropriation of $44,259,000 paid into the revolving fund from the Nuclear Physics program, plus collections of $58,162,821 to recover costs related to isotope production and isotope services. Collections in FY 2019 included, for example, sales of actinium-225, actinium-227, strontium-82, strontium-89, germanium-68, californium-252, helium-3, cobalt-60, nickel-63, selenium-75, and barium-133.

Actinium-225 (Ac-225) is used in pharmaceuticals under development to more effectively treat cancer and other diseases. Actinium-227 provides radium-223 for Xofigo®, which was 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. Strontium-82 has gained world-wide acceptance for use in heart imaging and strontium-89 alleviates the pain associated with bone metastases. Germanium-68 supports development of gallium-68 diagnostic imaging pharmaceuticals and the FDA-approved drug NETSPOT™ for detection of neuroendocrine tumors. Californium-252 has a variety of industrial applications, including oil and gas well-logging, and fission start-up in nuclear reactors; helium-3 is used in neutron detectors for national security and cryogenics; cobalt-60 is used in gamma-ray cancer surgery; nickel-63 enhances national security through its use in detectors for explosives and illicit material; selenium-75 is used as a radiography source; and barium-133 is a gamma-ray source used for calibration standards, including as a standard for iodine-131 for calibration of medical equipment.

In FY 2020, the DOE IP expects to sell about 160 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, eleven are high-volume isotopes often with commercial applications and the remaining are low-volume, mostly research isotopes, which are more expensive to produce. 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.

**Program Accomplishments**

*Eliminating U.S. Dependence on Foreign Supply.*

Strontium-90 is used as a generator of yttrium-90 which is used in medical applications such as the treatment of liver cancer. Until 2019, the U.S. had been dependent on Russia, the only world-wide supplier. The DOE IP is supporting an effort at PNNL to separate approximately 3,000 curies from legacy material. The first material was distributed to customers in 2019 and the DOE IP is now capable of fully meeting U.S. annual demand.

*Inventory of Scarce Isotope Created.*

The Enriched Stable Isotope Prototype Plant (ESIPP) at Oak Ridge National Laboratory completed its first production campaign for the rare isotope ruthenium-96 in FY 2019, generating the only ruthenium-96 available on the globe. Part of this inventory was used to enable a crucial nuclear physics experiment at Brookhaven's Relativistic Heavy Ion Collider to study matter that has not existed since the early Universe. The production was accomplished via electromagnetic separation technology. Efforts have now transitioned to ytterbium-176, another highly scarce isotope currently in demand to produce lutetium-177 for the treatment of prostate cancer.

*Commercialization of Strontium-82 (Sr-82) Production.*

The DOE IP worked with industry to establish the first domestic commercial producer of Sr-82, an isotope widely used for cardiac imaging. DOE IP introduced Sr-82 to the market decades ago, and has steadily increased production and the customer base to create an economically viable isotope, ready for commercialization. DOE IP provided technical assistance to private companies interested in developing Sr-82 production capabilities, and one was successful in entering the market in the U.S. DOE IP provided assistance in keeping them stable until their product was qualified to be used for FDA-approved cardiac imaging procedures. They are now the first domestic commercial producer of Sr-82, mitigating U.S. reliance on

Russian and Canadian producers. The DOE IP remains as a backup supplier, poised to cover any supply shortages, should they occur.

**Highlights of the FY 2021 Request**

For FY 2021, the Department foresees growth in isotope demand, with particular interest in alpha-emitters for cancer therapy and stable isotopes to exploit the newly established domestic production capabilities. The DOE IP portfolio continues to grow rapidly as isotope availability increases. The FY 2021 Request of $66,000,000 is an increase of $16,500,000, or 33.3 percent above the FY 2020 Enacted level. Revolving fund resources will be used to:

- maintain isotope production infrastructure and core competencies
- perform research and development on new isotope production and enrichment technology
- produce isotopes in short supply, add isotope harvesting to the Facility for Rare Isotope Beams (FRIB)
- enhance processing and production capabilities to increase isotope availability
- reduce U.S. dependence on foreign supply of isotopes, increase helium-3 extraction capabilities
- develop and operate radioisotope enrichment capabilities
- explore and enhance stable isotope enrichment capabilities
- increase production of Ac-225 and other high-in-demand alpha emitters for cancer therapy
- introduce new isotopes to the market for research and applications
- develop isotope production capabilities for quantum information science

The FY 2021 Request includes $3,500,000 to continue the FRIB Isotope Harvesting accelerator improvement effort. FRIB is a next generation scientific user facility being constructed at Michigan State University for nuclear structure and astrophysics measurements. This project will add isotope harvesting capabilities to the FRIB, which will provide access to a wide range of isotopes, including unusual isotopes for exploratory studies.

The FY 2021 Request for the Nuclear Physics program includes $12,000,000 to continue the U.S. Stable Isotope Production and Research Center at ORNL, which will significantly enhance stable isotope production capacity for the Nation. This Line Item Construction Project has a Total Project Cost (TPC) range of $200,000,000 - $260,000,000. This new facility will build upon the expertise in centrifuge and electromagnetic isotope separation technology nurtured by the Stable Isotope Production Facility (SIPF) major item of equipment.