

Isotope R&D and Production

Overview

The DOE Isotope Program's (DOE IP) mission is to:

- Produce and/or distribute stable isotopes and radioisotopes in short supply or unavailable in the United States, including related isotope services;
- Maintain mission readiness of critical national facilities, equipment, and core competencies needed to manufacture isotopes and ensure the U.S. is prepared to respond to supply chain gaps during a national crisis;
- Conduct R&D to develop transformative isotope production, separation, and enrichment technologies to enable federal, academic, and industrial innovation, research, and emerging technologies;
- Nurture an inclusive and diverse domestic workforce with unique and world-leading core competencies; and
- Mitigate U.S. dependence on foreign supplies of isotopes and promote robust domestic supply chains for U.S. economic resilience.

The DOE IP produces high priority radioactive and stable isotopes that are in short supply for the Nation or represent a supply chain risk due to reliance on countries that have been identified as “sensitive” by the DOE for policy reasons. The DOE IP is typically the only, or one of few, global producers for these isotopes. Isotopes are high priority, enabling commodities of strategic importance for the Nation and essential in medical diagnosis and treatment, discovery science, national security, advanced manufacturing, semiconductor manufacturing, space exploration, communications, biology, quantum information science, clean energy, and other fields. The DOE IP works closely with industry to ensure availability of isotopes for their economic stability and growth, and facilitates commercialization of isotope production to the domestic private sector. DOE IP continues operations during national emergencies to mitigate disruptions in isotope supply chains. DOE IP mitigates disruptions in supply chains critical to federal agencies, industry, and research during times of national crisis, such as the COVID-19 pandemic and the Russian invasion on Ukraine.

The DOE IP oversees the irradiation of targets at particle accelerators and nuclear research reactors at national laboratories and universities, which are then processed in radiochemical equipment to extract radioisotopes of interest; DOE IP also oversees extraction of radioisotopes from legacy waste or inventories to reduce waste disposition while providing a valuable product. DOE IP manages federal inventories of isotopes for the Nation, such as helium-3 (He-3), which is essential for cryogenics, quantum information science (QIS), fusion energy, and national security applications.

The DOE IP is responsible for the repository of stable isotopes that was produced by the calutrons developed as part of the Manhattan Project. The calutrons, mass spectrometers used for electromagnetic ion separation, ceased operations in 1998, which left the U.S. with no broad isotope enrichment capability. The U.S. inventory of stable isotopes is limited, requiring the U.S. to rely on foreign countries (mainly Russia) for critical stable isotopes. One of the DOE IP's highest priorities is to develop modern stable isotope enrichment capabilities to rebuild domestic manufacturing capabilities, replenish inventories, and promote U.S. economic resilience, prosperity, and competitiveness.

The DOE IP supports a world-leading R&D program in innovative isotope production, enrichment, and chemical separations. Isotope manufacturing and R&D activities provide collateral benefits for training and workforce development, and promotion of a future U.S.-based expertise relevant to clean energy, accelerator science, nuclear engineering, nuclear physics, isotope enrichment, and radiochemistry. These disciplines are foundational, not only to isotope production and processing, but they also underpin many essential aspects of basic and applied nuclear and radiochemical science R&D and production activities develop and employ techniques and platform technologies in artificial intelligence (AI), machine learning (ML), robotics, and advanced manufacturing.

The FY 2025 Request supports mission readiness of facilities, expert staff, and related equipment focused on addressing isotope shortages; innovative research; and new capabilities to meet the Nation's growing demand for isotopes. Customer collections from sales will pay for the actual production and distribution of the isotope and related services. Isotopes sold to commercial customers and allied foreign entities will be priced at full-cost recovery or market price (whichever is higher). Isotope pricing for domestic research will be reduced to promote innovation and scientific advances.

Highlights of the FY 2025 Request

The FY 2025 Request for \$183.9 million is an increase of \$74.4 million over the FY 2023 Enacted. In FY 2025, the DOE IP anticipates mounting supply disruptions of critical and high-impact isotopes. Supply chains are increasingly vulnerable since the Russian invasion of Ukraine. Demand in both radio and stable isotopes continues to increase for high priority national applications and technologies such as nuclear batteries, power sources, clean energy technologies, semiconductor and microelectronics manufacturing, quantum computing, next generation advanced fission and fusion reactors, and medical treatment and diagnosis of cancer and other infectious diseases.

The FY 2025 Request increases support for operations of all isotope production facilities to 85 percent optimal and supports essential workforce to respond more efficiently to fill gaps in critical isotope supply chains. A newly refurbished low energy medical cyclotron at Brookhaven National Laboratory (BNL) will ramp up to increase the availability of actinium-225, a medical isotope that is showing success in treating metastasized cancers. The Request provides support to address high priority deferred maintenance and single point failures to increase safe, robust, and reliable operations across production sites. FY 2025 funding supports increased staffing at the National Isotope Development Center (NIDC), the business arm of the DOE IP, to address the rapidly increasing interfaces with the domestic and allied international stakeholder community.

The FY 2025 Request includes support for the start of operations of the Stable Isotope Production Facility (SIPF) Major Item of Equipment (MIE) to operate the Nation's first full-scale and modern gas centrifuge cascade for enrichment of stable isotopes; SIPF will first produce xenon-129 (Xe-129) for polarized lung imaging and diagnosis of infectious disease. Scientists and engineers will assemble and commission new electromagnetic ion separation (EMIS) devices to enrich high priority stable isotopes. The Program will advance towards the development of a heavy water inventory, enabled by Inflation Reduction Act (IRA) funding. The DOE IP will address high risk isotopes, including helium-3 for quantum computing and strontium-90 for nuclear batteries and medical applications.

The DOE IP will re-prioritize research and development investments in FY 2025, focusing on the development of isotopes with the deepest impact to the lives of U.S. taxpayers and U.S. national security. The Reaching a New Energy Sciences Workforce (RENEW) and Funding for the Accelerated, Inclusive Research (FAIR) initiatives will increase to continue DOE IP efforts to advance equity and inclusion of underserved communities and emerging research institutions as well as HBCUs and MSIs in SC-sponsored research. The DOE IP involvement in the Biopreparedness Research Virtual Environment (BRaVE) will enhance national preparedness with investment in equipment and research to produce isotopes for biology, biomedicine, and that strengthen the Nation's response when in a pandemic or other medical emergency. Investments in microelectronics will support research to produce isotopes needed for semiconductor manufacturing. The Request includes continued support of research to advance the production of isotopes of interest for quantum computing.

In FY 2025 the Facility for Rare Isotope Beams (FRIB) harvesting effort at Michigan State University (MSU) will complete the transition to routine operations and will extract and process rare isotopes from the FRIB beam dump for research purposes. The Request increases support for the University Isotope Network (UIN), which recently expanded to include the University of Wisconsin-Madison and Texas A&M University.

The FY 2025 Request includes \$45.9 million in Total Estimated Cost (TEC) funding to advance the Stable Isotope Production and Research Center (SIPRC). DOE, in coordination with Oak Ridge National Laboratory (ORNL), held a groundbreaking in October 2022 for the SIPRC, which will expand the nation's capability to enrich stable isotopes for medical, industrial, and research applications, mitigating U.S. dependence on sensitive countries. The Request continues design for the Radioisotope Processing Facility (RPF) to address a lack of available radiochemical processing equipment to mitigate U.S. dependency on sensitive foreign supply chains of radioisotopes. Funding supports preliminary engineering design for the Clinical Alpha Radionuclide Producer (CARP) facility retrofit and equipment, to increase availability of high demand medical isotopes and address disruptions in global isotope supply chains.

**Isotope R&D and Production
Funding**

(dollars in thousands)

	FY 2023 Enacted	FY 2024 Annualized CR	FY 2025 Request	FY 2025 Request vs FY 2023 Enacted
Isotope R&D and Production				
Isotopes, Research	38,827	57,288	43,629	+4,802
Isotopes, Operations	46,624	75,363	91,371	+44,747
Subtotal, Isotope R&D and Production	85,451	132,651	135,000	+49,549
Construction				
20-SC-51 U.S. Stable Isotope Production and Research Center (SIPRC), ORNL	24,000	20,900	45,900	+21,900
24-SC-92 Clinical Alpha Radionuclide Producer (CARP), BNL	–	–	1,000	+1,000
24-SC-91 Radioisotope Processing Facility, ORNL	–	–	2,000	+2,000
Subtotal, Construction	24,000	20,900	48,900	+24,900
Total, Isotope R&D and Production	109,451	153,551	183,900	+74,449

Basic and Applied R&D Coordination

Coordination and integration are vital in ensuring that critical isotopes are available to achieve the mission of federal agencies and organizations, industrial applications, and enable federal R&D goals. Isotopes are vital to federal agencies, including the National Institutes of Health (NIH), National Aeronautics and Space Administration (NASA), Department of Defense (DoD), Office of the Director of National Intelligence (ODNI), National Institute of Standards and Technology (NIST), Federal Bureau of Investigations (FBI), Department of Agriculture, Department of Homeland Security (DHS), National Science Foundation (NSF), and DOE. DOE IP conducts the biennial Workshop on Federal Isotope Supply and Demand to collect 5-year projections from all federal agencies to ensure adequate supply and evidence-based Program priorities. DOE IP effectively coordinates and communicates on isotope supply and demand at the federal level through participation in Federal and Interagency Working Groups, White House Office of Science and Technology Policy (OSTP) Subcommittees, National Security Council meetings, and White House Small Group and Inter Policy Committees; the DOE IP also leads the Interagency Group on He-3 to determine an annual federal allocation of He-3 from reserves in support of federal missions. DOE IP interacts closely and partners frequently with other DOE Offices on domestic supply chains of valuable isotopes; a few examples are the extraction of americium-241 for batteries from plutonium waste streams (NNSA); the provision of He-3 for cryogenics from tritium beds (NNSA); the detritiation of heavy water from legacy stockpiles and the provision of strontium-90 from legacy inventories from Environmental Management (EM); the extraction of promethium-147 for nuclear batteries from plutonium-238 waste streams (NE); and the recovery of krypton-85 for semiconductor manufacturing during spent fuel reprocessing (NE). In all these examples, the only other producer of these isotopes is Russia.

The DOE IP, along with the NIDC, meet throughout the year with industrial stakeholders to gauge the health of global supply chains. The Program also attends industry-organized meetings and roundtables to report on supply chain stability and sets up a Program booth at expositions at professional society meetings to promote communication and conduct outreach. The DOE IP is in the process of establishing a new Federal Advisory Committee, the Isotope R&D and Production Advisory Committee (IRDPAAC), to provide guidance to the Program and aid in the development of priorities and long-range plans. Membership diversity will be balanced for demographics, disciplines, and stakeholder interests.

While the DOE IP is not responsible for the production of molybdenum-99, which is a widely used isotope in diagnostic medical imaging in the Nation, it works closely with NNSA, the lead entity responsible for domestic molybdenum-99 production, offering technical and management support. SIPRC will produce molybdenum-98 and molybdenum-100, precursors to certain molybdenum-99 production routes to ensure domestic supply chain resilience.

Program Accomplishments

Iridium-192 Domestic Supply Chain Underway to Mitigate DOD and other Reliance on Sensitive Countries

Iridium-192 (Ir-192) enables timely on-site radiography of metal welds to identify weaknesses in the same manner as an X-ray examines human skeletal structure. 100% of this Ir-192 has been sourced from foreign countries for over 20 years, including heavy reliance on sensitive countries. By working with ORNL and a U.S. company, DOE IP has arranged to restart domestic supply of this vital material, which will meet 30-50% of the U.S. market. This will support ongoing radiography inspections for Department of Defense ship building, piping for electrical energy plants, as well as bridge & railroad systems. Reducing foreign reliance is even more important as demand for radiography is increasing in the presence of green energy projects and expanding space exploration.

Cutting-edge System to Transform Most Any Metal into a Spherical Powder

ORNL's Stable Isotope Materials and Chemistry Group has installed a newly designed, cutting-edge system to transform most any metal into a spherical powder. To date, 25 unique elements and 5 alloys have been transformed into metal powders including uncommon elements that have important applications for our nation. Each powder sphere is nearly identical from particle to particle. While these metals are technically still solid, the powder grains roll like tiny ball bearings giving nearly any material the behavior of a free-flowing liquid. Unlike traditional powders, these can be injected or pumped to enable automated materials handling for advanced manufacturing processes. This emergent flow property is also enabling new concepts for nuclear batteries for defense and space initiatives. Handling solids like liquids is opening new capabilities for medical isotope production research. Improved production of powerful isotopes will better enable new cancer treatments.

Innovative Approach to Supplying Scandium-44, a Medically Relevant Diagnostic Isotope

Scandium-44 (Sc-44) is a promising medical isotope for positron emission tomography (PET) imaging allowing doctors to identify cancer, heart disease, and other conditions. The isotope can be produced through the radioactive decay of titanium-44 (Ti-44), and since it decays much more slowly than Sc-44, the same batch of Ti-44 can theoretically produce enough Sc-44 for many years of PET scans. The challenge has been to reliably and repeatably separate Sc-44 from Ti-44 in a hospital setting. BNL researchers have developed a new solution by synthesizing a chemical compound to attach the Ti-44 on a resin and fill a cylinder with it. By passing a specific liquid through the resin filled cylinder they found they were able to remove the Sc-44 and leave the Ti-44 behind on the resin. The invention is called a radioisotope generator since the process can be repeated as more scandium-44 is produced each day; and its portability and simplicity make it ideal for a hospital setting, where generators for other isotopes are already in use. The DOE IP supports this and other research and development efforts on Sc-44 radioisotope production at several facilities. DOE IP's goal is to make several scandium radioisotopes routinely and widely available in the near-term. With BNL's innovative approach, Sc-44 is one step closer to being evaluated for use in medical procedures.

Domestic Supply Chains Established for Biomedical Research

DOE IP established domestic production of many isotopes in response to the Russian war induced radioisotope supply chain disruption. Two examples include the production of iron-59 (Fe-59) and manganese-54 (Mn-54) which were commonly sourced from Russia prior to 2022. MURR has established routine production of these isotopes, and they are now offered for sale to the Nation through the DOE IP. Both isotopes are commonly used in biomedical research. Fe-59 is used in vitro and in vivo analyses of iron uptake, metabolism, and excretion studies. Mn-54 is a radioisotope commonly used as a radiotracer in biomedical research as well as environmental remediation. MURR is now supporting nationwide availability of these radioisotopes, establishing new domestic supply chains for these novel products.

Getting Purer Berkelium, Faster Than Ever

Berkelium's (Bk) primary use is in heavy element research to enable basic discovery science. Its most stable isotope, Bk-249, played a significant role in the creation and subsequent discovery of super-heavy element 117, tennessine (Tn). However, researchers often need better ways to extract individual heavy metal elements, called actinides, to obtain purer end products. A new separation technique developed by researchers at ORNL has accomplished just that and produced the world's purest Bk-249 to date. The new method is also much faster and easier to employ than previous methods, reducing the processing time from eight weeks to just eight days. The technique has synergies with other missions within the Federal Complex in that separation of individual actinides is essential for improving nuclear fuel recycling and nuclear waste management. Further research could lead to amplification of the production of other rare heavy actinide isotopes like einsteinium (Es) and fermium (Fm), the supply of which is currently dictated by the production cadence of other isotopes.

Isotope R&D and Production

Description

The DOE IP consists of three main components: research, operations, and line-item construction projects.

Research

Research funding at national laboratories and universities for both stable and radioisotopes supports core research groups, competitive research opportunities, SC research initiatives, operations mission readiness of the university facilities (a core competency of staff and maintained equipment for isotope production), university research projects, Other Project Costs (OPC) of construction projects, and workforce development. Core research aims to develop new production pathways or improve the efficiency, reliability, and/or cost-effectiveness of existing processes.

The DOE IP supports core research groups at Argonne National Laboratory (ANL), Brookhaven National Laboratory (BNL), Los Alamos National Laboratory (LANL), ORNL, and Pacific Northwest National Laboratory (PNNL) to conduct innovative research for novel or advanced production and chemical separation techniques for critical isotopes. Core research support is also provided to the UIN institutions; these universities provide domestic supply chains primarily to strengthen the Nation's research competitiveness and play an important role in workforce development. The UIN is currently comprised of the University of Washington (UW) Cyclotron, the University of Missouri Research Reactor (MURR), FRIB Isotope Harvesting at MSU, University of Alabama-Birmingham (UAB), University of Wisconsin-Madison (UWM), and Texas A&M University (TAMU). These universities have unique capabilities, such as the UW and TAMU multi-particle cyclotrons, where full-scale production of the alpha-emitter astatine-211 has been developed for cancer therapy. MURR boasts the highest flux university research reactor in the United States, and DOE IP uses MURR to produce multiple isotopes, including lutetium-177 for cancer therapy research. The UAB cyclotron includes four beamlines and associated target stations to produce a variety of radioisotopes, and has hot cells designated for the preparation of human use and preclinical radiopharmaceuticals. Harvesting of isotopes from the beam dump of the nuclear physics facility, FRIB, is an innovative approach to repurpose unwanted waste into valuable assets for U.S. research. The UWM cyclotron distributes a variety of isotopes and provides target fabrication expertise for the UIN.

A priority of the DOE IP is to develop a broad national stable isotope enrichment core competency as enriched stable isotopes are foundational to many applications, including the production of all radioisotopes. The production of each enriched stable isotope requires an intense research campaign. Core research funding for stable isotopes is provided to both ORNL and PNNL. In addition, machines are designed and optimized for isotopes of interest for quantum computing as part of the SC QIS Initiative. The development of Atomic Vapor Laser Ion Separation (AVLIS) at Lawrence Livermore National Laboratory is supported to promote clean energy by considering isotopically tailored low activation materials for fusion and fast fission nuclear reactors, and enrichment of isotopes that can yield fuel cycle cost savings and reduced nuclear waste.

Competitive research funds to universities and national laboratories support targeted activities, including research to develop novel isotopes of interest to U.S. stakeholders and establish domestic isotope supply chains. An example is heavy water (hydrogen replaced with deuterium), last produced domestically in 1981. Deuterium is disassociated from heavy water and is used in deuterated drugs products, biomedical research, fusion energy research, and semiconductor manufacturing. Foreign supply is fragile, and the DOE IP is developing technology to detritiate legacy heavy water at Savannah River National Laboratory (SRNL). Other examples of competitive research topics include the production of isotopes for next-generation advanced fission reactors (including molten salt) and fusion reactors, innovative medical isotopes, new sources of helium-3 for cryogenics, rare isotopes for nuclear forensics, critical nuclear data measurements, radioisotope enrichment technology, targetry, modular automated systems, robotics, and the application of machine learning and artificial intelligence to isotope production.

Another high priority area of research is the development of transformative medical isotopes to both diagnose and treat disease, reducing cancer mortality. Globally, there is escalating interest in alpha and beta emitters for revolutionary cancer and infectious disease therapy and diagnostics. The DOE IP is typically the sole global source for many of these isotopes or leading the way in innovative research and manufacturing to make them available. DOE IP remains committed to the production of alpha-emitters, including Ac-225. The ability to meet U.S. demand will require expansion of radiochemical

processing infrastructure. Support for OPC for the Clinical Alpha Radionuclide Producer facility (CARP) advances new chemical processing capabilities at BNL, so that additional life-saving isotopes can be provided to U.S. patients, reducing cancer mortality. In coordination with the NIH, the DOE IP supports the basic science research that facilitates the transition of novel radioisotopes and targeted delivery agents from the laboratory to use in clinical trials for both diagnosis and treatment of disease.

As part of the SC BRaVE Initiative, national preparedness is enhanced with equipment and research to produce medical isotopes pertinent to biology, biomedicine, and the diagnosis and treatment of infectious disease to increase performance and response times during times of national crisis. Participation in the Microelectronics initiative enables a close examination of the isotopes that are needed for semiconductor manufacturing and subsequent research to consider the technology and radiochemistry needed for their production. Training and development opportunities for students and post-docs are a priority for DOE IP to promote a vibrant, inclusive, and diverse workforce essential for isotope production. DOE IP participates in the RENEW initiative to expand targeted efforts, including a RENEW graduate fellowship, to broaden participation in underserved communities, and advance equity and inclusion at emerging research institutions, HBCUs and MSIs. Participation in the SC FAIR initiative provides opportunities for research, bolstered with investments in equipment and infrastructure at emerging research institutions, HBCUs and MSIs, including attention to underserved communities.

DOE IP sponsors workshops at professional society meetings to promote communication of advances in isotope availability, research & development, and production, and invests in the Nation's future nuclear chemistry and biomedical researchers through support for the Nuclear Chemistry Summer School (NCSS) program. The NCSS, jointly supported with SC's Basic Energy Sciences (BES) and Nuclear Physics (NP) programs, consists of an intensive six-week program of formal accredited lectures on the fundamentals of nuclear science, radiochemistry, and their applications in related fields, as well as laboratory practicums focusing on state-of-the-art instrumentation and technology used routinely in basic and applied nuclear science.

Facility Operations

Facility operations supports activities at national labs: mission readiness at reactor, accelerator, and enrichment facilities; mission readiness supports the core group of expert staff required to manage, operate, and maintain the facilities and related equipment to produce isotopes, and the investments required to ensure safe, cost-effective, and reliable operations. Facility operations also supports equipment for chemical processing (such as hot cells and glove boxes); pre-operations of stable isotope equipment; inventory management and dispensing activities; management and maintenance of advanced manufacturing capabilities; operations support and assembly; and support of the NIDC, the business arm of the DOE IP.

The DOE IP relies on the Isotope Production Facility (IPF) at LANL and the Brookhaven Linac Isotope Producer (BLIP) facility at BNL; both are proton accelerators that, in combination, provide year-round continuous availability of medical radioisotopes. The IPF operates concurrently with the NNSA Los Alamos Neutron Science Center facility and BLIP operates concurrently with the Relativistic Heavy Ion Collider, and soon the Electron Ion Collider. The LEAF at ANL is the only electron accelerator in the Program and provides unique pathways for producing medical radioisotopes. The DOE IP utilizes the capabilities of two research reactors, the High Flux Isotope Reactor (HFIR) at ORNL stewarded by the SC Office of Basic Energy Sciences and the Advanced Test Reactor at INL, stewarded by the Office of Nuclear Energy. Related chemical processing and handling equipment is supported at these sites. In addition, processing capabilities are supported at PNNL for targeted isotopes such as strontium-90 for batteries and medical applications, radium-226 to produce Ac-225, and lead-212 isotope generators for cancer treatments. At the Y-12 National Security Complex, DOE IP supports the preparation and packaging of lithium isotopes and uranium-235 for industry and research, and americium-241 for nuclear sources and batteries is recovered from NNSA plutonium processes at the LANL Plutonium Facility. He-3 for cryogenics is extracted from NNSA-owned tritium beds at the Savannah River Site, and the radioisotope separator at INL enriches radioisotopes for nuclear forensics. Individual electromagnetic ion separators are assembled and operated at ORNL as the country awaits SIPRC to provide substantial capability.

The NIDC is located at ORNL and is responsible for the day-to-day business operations for the DOE IP, including sales, contract negotiation, marketing assessments, public outreach, quality control, packaging, and transportation. The NIDC

arranges for regular and frequent interfaces between DOE IP and industrial, academic, and medical communities to ensure that strategies are evidence-based and informed by stakeholder interactions. Furthermore, the DOE IP formally canvasses the broad federal community for isotope demands every other year to align priorities with evidence-based program evaluations.

The DOE IP provides over 260 stable isotopes from inventory, produces a few stable isotopes, and produces ~100 radioisotopes in short supply for the Nation. Some examples of produced isotopes by the DOE IP are:

- actinium-225, actinium-227, astatine-211, cerium-134, scandium-47, scandium-44, holmium-166m, tungsten-188, lutetium-177, strontium-89, strontium-90, tin-117m, vanadium-48, manganese-52, manganese-54, gold-199, cobalt-55, and cobalt-60 for cancer therapy and imaging diagnostics
- californium-252 for nuclear reactor start-up, oil and gas exploration and production well logging
- arsenic-73, iron-52, iron-59, and zinc-65 as tracers in metabolic studies
- barium-133 for quantum computing research, medical standards, and industrial sources
- berkelium-249, americium-243, uranium-238, plutonium-242, plutonium-244, californium-249, californium-251, einsteinium-254, and curium-248 for use as targets for discovery of new super heavy elements
- bismuth-213, lead-212, lead-203, astatine-211, copper-67, thorium-227, thorium-228, radium-223, and radium-224 for cancer and infectious disease therapy and research
- cadmium-109 for X-ray fluorescence imaging and environmental research
- fermium-257 for heavy element chemistry research
- helium-3 for cryogenics and radiation detection
- lithium-6 neutron detectors for homeland security applications
- iridium-192, selenium-75 for industrial radiography
- silicon-32 for oceanography and climate modeling
- ytterbium-171 for quantum memory
- ytterbium-176 as feedstock for isotopes that treat prostate cancer
- nickel-63 for explosives detection
- strontium-90, promethium-147, americium-241, and thulium-170 for nuclear batteries and power sources

It can take decades for an economically and technically viable commercial market to be developed for any novel isotope. The DOE IP works closely with industry to commercialize technology and promote domestic independent producers in a smooth transition that does not disrupt supply and/or prohibit research. At that point, the DOE IP stops production to not compete with the domestic industry. Examples in which domestic commercial production now exists include strontium-82 for cardiac heart imaging and germanium-68 for medical diagnostics.

Projects

DOE IP-supported research demonstrated the feasibility of new EMIS and gas centrifuge (GC) technologies and re-established a prototype general enriched stable isotope production capability in the U.S. The subsequent SIPF Major Item of Equipment (MIE) at ORNL establishes the first full-scale GC cascade to enrich stable isotopes. The implementation of SIPF nears its planned completion in FY 2025 and shifts to operations to produce enriched xenon-129. Xenon-129 has demonstrated effectiveness in polarized lung imaging and there is currently no U.S. production capability. This isotope has also garnered the interest of the medical community in monitoring lung function and damage from infectious diseases such as COVID-19.

The DOE IP is implementing three projects to mitigate U.S. dependency on isotope supply chains from sensitive countries and fill gaps in rare medical isotope supplies. The SIPRC project re-establishes large-scale stable isotope enrichment in the United States to compete with those of Russia and China. The Radioisotope Production Facility will meet the critical need to remove U.S. dependence on Russia for high-impact radioisotopes. The CARP facility makes available highly sought-after cancer therapeutics and diagnostics.

Isotope R&D and Production

Activities and Explanation of Changes

(dollars in thousands)

FY 2023 Enacted	FY 2025 Request	Explanation of Changes FY 2025 Request vs FY 2023 Enacted
Isotope R&D and Production	\$109,451	\$183,900
	+\$74,449	
Isotopes, Research	\$38,827	\$43,629
		+\$4,802
<p>Funding supports high impact R&D activities at universities and national laboratories leading to advanced, innovative, and novel isotope production and processing technologies, increasing the availability of isotopes in short supply and promote U.S. economic resilience. The priority R&D remains on the development of full-scale processing and technology capabilities for the production of alpha- and beta-emitters for cancer therapy, of which the DOE IP is a global leader, and to promote their transition to medical applications. Funding maintains the University Isotope Network to perform the R&D necessary to enable routine production. Research to develop enrichment capability for new stable isotopes of importance, including isotopes for clean energy and quantum computing is maintained. Participation in the Advanced Manufacturing initiative continues with innovative isotope production technology that can facilitate commercial engagement and the promotion of domestic supply chains, such as “desktop” inkjet printing of production targets. Support for the DOE IP Traineeship Program with a goal to increase the diversity of the workforce as part of RENEW increases in FY 2023. Research increases for the BRaVE initiative in partnership with the University of Missouri to address a single point failure in reactor isotope processing and create tech-savvy jobs in an underserved rural area of Missouri with the implementation of the Radioisotope Science Center at</p>	<p>Core research supports the highest impact R&D activities at universities and national laboratories to strengthen the Nation’s scientific and technical strengths. Competitive research focusses on efforts to urgently establish domestic supply chains that have been disrupted by the Russian invasion of Ukraine. Six universities participate in the UIN to produce unique isotopes and promote workforce development. Efforts to develop isotopes for clean energy applications and quantum computing continue. Participation in the SC initiatives RENEW and FAIR, BRaVE, and Microelectronics increases. Research funding enables support of the Nuclear Chemistry Summer School and participation in the SC Early Career Awards Program. Support for OPC activities of the CARP facility, to increase availability of rare medical isotopes that are revolutionizing cancer therapy.</p>	<p>The increase supports prioritized, evidence-based research activities that will improve or develop innovative isotope production, enrichment, and processing technology with the goal of increasing domestic supplies of critical isotopes for medicine, and national security. Specific activities include continued support of the Nuclear Chemistry Summary School and participation in the SC Early Career Awards Program; and OPC support for CARP conceptual design activities; support for RENEW and FAIR increases.</p>

(dollars in thousands)

FY 2023 Enacted	FY 2025 Request	Explanation of Changes FY 2025 Request vs FY 2023 Enacted
<p>MURR. Design for the ORNL RPF project continues to advance needed chemical processing infrastructure at ORNL. Research to advance isotope harvesting capabilities and expertise at FRIB are roughly maintained. Funding supports participation in the Accelerate initiative which supports scientific research to accelerate the transition of isotope science advances to clinical trials. Also, funding supports the FAIR initiative which provides focused investment on enhancing isotope research on clean energy, climate, and related topics at minority serving institutions, including attention to underserved and environmental justice regions.</p>		
<p>Isotopes, Operations</p>	<p>\$46,624</p>	<p>\$91,371</p>
<p>Funding supports mission readiness (~80 percent optimum) of the growing portfolio of isotope production and processing sites and nurtures critical core competencies in isotope production and development, promoting robust domestic supply chains for cancer therapy and other applications. Support maintains NIDC activities to interface with the growing stakeholder community and rapidly expanding isotope portfolio. Funding continues to support electromagnetic separation technology optimized to heavy elements, enriched radioisotope separation technology, extraction of valuable isotopes from legacy Mark 18-A.</p>	<p>The Request will support increased mission readiness at all production and processing sites to 85 percent enabling the Program to fill gaps in isotope supply chains and develop new domestic sources of critical isotopes. Funding will continue to support EMIS implementation and operations, and development of other enrichment core competencies. The SIPF, the first full-scale gas centrifuge cascade for enriching stable isotopes, will begin operation. The newly refurbished cyclotron at BNL transitions to routine operations. Investments target high priority single point failures at the production sites as well as deferred maintenance.</p>	<p>The funding increase will support mission readiness to increase from approximately 80 to 85 percent. Evidence-based activities will support increased readiness to produce stable isotopes and establish a core competence in stable isotope operations; additional staff commission and operate new machines. The SIPF will begin producing Xe-129 for the diagnosis of infectious lung diseases. The new BNL cyclotron ramps up production of Ac-225 for the treatment of metastasized cancers. NIDC will add staff to keep pace with growing inquiries. Support will increase for the inventory management and unique dispensing of stable isotopes in special forms. Support will increase for the extraction of isotopes from the Mark 18-A legacy targets. Increased funding will address the highest priority efforts in a backlog of deferred maintenance and performance improvements to increase safe, reliable, and efficient operations.</p>
		<p>+ \$44,747</p>

Isotope R&D and Production Construction

Description

The DOE Isotope Program (DOE IP) works with federal agencies and industry to mitigate disruptions in critical isotope supply chains from the ongoing Russian invasion of Ukraine and subsequent sanctions. DOE IP is investing in new capabilities to meet U.S. demand and reduce dependence on sensitive countries. These new facilities will allow the United States to increase processing capability and expand production of critical isotopes.

24-SC-91, Radioisotope Processing Facility (RPF)

To mitigate radioisotope dependence on geopolitically sensitive countries, and to meet U.S. demand for critical isotopes and establish domestic supply chains, it is critical to expand U.S. radioisotope processing capacity at the Radioisotope Processing Facility (RPF) at ORNL. The RPF is planned as a Hazard Category 2 nuclear facility outfitted with specialized equipment able to process the higher specific activity targets that are irradiated in a reactor, such as HFIR. The project received CD-0, Approve Mission Need, approval on April 29, 2021. The project is working to achieve CD-1/3A, Approve Alternative Selection and Cost Range, planned for FY 2024. The CD-0 approved TPC range is \$310,000,000 to \$615,000,000.

24-SC-92, Clinical Alpha Radionuclide Producer (CARP)

The Clinical Alpha Radionuclide Producer (CARP) will allow the U.S. to be competitive with geopolitically sensitive countries in the production of innovative medical isotopes to diagnose and treat cancer and ensure that U.S. taxpayers have access to life-saving medical treatments and diagnostics. Once operational, CARP will significantly increase the amount of radioisotopes that the U.S. can process, the batch sizes, and the concurrent chemical processing activities at the Brookhaven Linac Isotope Producer (BLIP). The CARP facility will include specialized chemical processing equipment and building modifications at BNL for the processing of accelerator-irradiated targets. CARP will cost-effectively repurpose an existing nuclear Hazard Category 3 Building and outfits it with hot-cells and supporting equipment. Not only will CARP allow the domestic establishment of new accelerator-produced isotopes currently only produced outside of the U.S., but it will also enable an increase in the availability of highly sought-after alpha-emitting isotopes to decrease cancer mortality. CARP received CD-0, Approve Mission Need, approval on December 5, 2022, with a CD-0 approved TPC range of \$60,000,000 to \$80,000,000.

20-SC-51, U.S. Stable Isotope Production and Research Center (SIPRC)

The Stable Isotope Production and Research Center (SIPRC) will reinstate versatile, large-scale stable isotope enrichment capacity in the United States. Russia is the major producer of most stable isotopes and China is an emerging leader. The current capacity within the U.S. is insufficient to meet the Nation's growing demands and the current inventory of stable isotopes is being depleted. SIPRC will address U.S. stable isotope needs in an economical and operationally efficient manner. Once constructed, SIPRC will provide critical isotopes for industry, medicine, and national security. The SIPRC line-item construction project will expand gas centrifuge isotope separation and EMIS production capability. SIPRC received CD-1, Approve Alternative Selection and Cost Range, and Subproject-1 CD-3A, Approve Long Lead Procurement, approvals on November 4, 2021. The project received approval for Subproject-1 CD-3B, Approve Long Lead Procurement, on July 19, 2023. The Total Project Cost (TPC) point estimate is \$325,000,000 with a preliminary TPC range of \$187,000,000 to \$338,000,000, approved at CD-1. Impacts of rising construction costs and supply chain challenges were assessed and validated at evidence-based peer reviews in 4Q FY 2023.

**Isotope R&D and Production
Construction**

Activities and Explanation of Changes

(dollars in thousands)

FY 2023 Enacted	FY 2025 Request	Explanation of Changes FY 2025 Request vs FY 2023 Enacted
Construction	\$24,000	\$48,900
		\$24,900
24-SC-91, Radioisotope Processing Facility (RPF)	\$ —	\$2,000
No funding requested.	The Request will support TEC of the RPF at ORNL. RPF will address a lack of available radiochemical processing infrastructure within the DOE IP complex for reactor target processing which inhibits production of critical isotopes. RPF will mitigate U.S. dependence on foreign radioisotope supply chains.	The increase will provide TEC funding to support preliminary engineering design.
24-SC-92, Clinical Alpha Radionuclide Producer (CARP)	\$ —	\$1,000
No funding requested.	The Request will support TEC of the CARP at BNL. CARP will enable the domestic establishment of new accelerator-produced isotopes currently only produced outside of the United States and will allow increase availability of highly sought after alpha-emitting isotopes to decrease cancer mortality and meet U.S. demand.	The increase will provide TEC funding to support engineering design to repurpose an existing facility at BNL and will add chemical processing equipment.
20-SC-51, U.S. Stable Isotope Production and Research Center (SIPRC)	\$24,000	\$45,900
Funding supports the continuation of engineering design and approved long lead procurements of the U.S. SIPRC.	Funding will continue design and construction of the U.S. SIPRC at ORNL, according to project plans, to provide large scale stable isotope production capacity for the Nation and mitigate U.S. dependence on foreign capabilities.	TEC funding will prioritize construction for the conventional facility and procurement of EMIS components, while continuing design of gas centrifuges.
		+\$21,900

**Isotope R&D and Production
Capital Summary**

(dollars in thousands)

	Total	Prior Years	FY 2023 Enacted	FY 2024 Annualized CR	FY 2025 Request	FY 2025 Request vs FY 2023 Enacted
Capital Operating Expenses						
Capital Equipment	N/A	N/A	2,000	9,100	3,029	+1,029
Minor Construction Activities						
General Plant Projects	N/A	N/A	–	–	3,042	+3,042
Accelerator Improvement Projects	N/A	N/A	–	–	3,029	+3,029
Total, Capital Operating Expenses	N/A	N/A	2,000	9,100	9,100	+7,100

**Isotope R&D and Production
Construction Projects Summary**

(dollars in thousands)

	Total	Prior Years	FY 2023 Enacted	FY 2024 Annualized CR	FY 2025 Request	FY 2025 Request vs FY 2023 Enacted
24-SC-91, Radioisotope Processing Facility, ORNL						
Total Estimated Cost (TEC)	569,900	-	-	-	2,000	+2,000
Other Project Cost (OPC)	15,600	13,600	1,000	1,000	-	-1,000
Total Project Cost (TPC)	585,500	13,600	1,000	1,000	2,000	+1,000
24-SC-92, Clinical Alpha Radionuclide Producer (CARP), BNL						
Total Estimated Cost (TEC)	69,000	-	-	-	1,000	+1,000
Other Project Cost (OPC)	10,500	-	585	2,000	1,000	+415
Total Project Cost (TPC)	79,500	-	585	2,000	2,000	+1,415
20-SC-51, U.S. Stable Isotope Production and Research Center (SIPRC), ORNL						
Total Estimated Cost (TEC)	289,800	87,000	24,000	20,900	45,900	+21,900
Other Project Cost (OPC)	5,600	3,200	-	-	-	-
Total Project Cost (TPC)	295,400	90,200	24,000	20,900	45,900	+21,900
Total, Construction						
Total Estimated Cost (TEC)	N/A	N/A	24,000	20,900	48,900	+24,900
Other Project Cost (OPC)	N/A	N/A	1,585	3,000	1,000	-585
Total Project Cost (TPC)	N/A	N/A	25,585	23,900	49,900	+24,315

Notes:

- The total preliminary TPC for the U.S. Stable Isotope Production and Research Center (SIPRC) of \$295,400,000 does not include \$29,600,000 (\$24,000,000 TEC and \$5,600,000 OPC) included in the Nuclear Physics program for prior years. The full preliminary total for SIPRC, combining the Nuclear Physics and Isotope R&D and Production funding, is \$325,000,000. This project is not baselined.
- The total preliminary TPC for the Radioisotope Processing Facility (RPF) of \$614,406,000 does not include \$594,000 in OPC funding included in the Nuclear Physics program for prior years. The full CD-0 approved total for RPF, combining the Nuclear Physics and Isotope R&D and Production funding, is \$615,000,000. This project is not baselined.

**Isotope R&D and Production
Scientific Employment**

	FY 2023 Enacted	FY 2024 Annualized CR	FY 2025 Request	FY 2025 Request vs FY 2023 Enacted
Number of Permanent Ph.Ds (FTEs)	41	57	72	+31
Number of Postdoctoral Associates (FTEs)	30	34	36	+6
Number of Graduate Students (FTEs)	33	45	49	+16
Number of Other Scientific Employment (FTEs)	103	140	215	+112
Total Scientific Employment (FTEs)	207	276	372	+165

Note:

- *Other Scientific Employment (FTEs) includes technicians, engineers, computer professionals and other support staff.*

**24-SC-91, Radioisotope Processing Facility (RPF)
Oak Ridge National Laboratory, ORNL
Project is for Design and Construction**

1. Summary, Significant Changes, and Schedule and Cost History

Summary

The FY 2025 Request for the Radioisotope Processing Facility (RPF) is \$2,000,000 of Total Estimated Cost (TEC) funding. The preliminary Total Project Cost (TPC) point estimate is \$425,300,000 with a CD-0 approved TPC range of \$310,000,000 to \$615,000,000.

Significant Changes

This project data sheet (PDS) is an update of the FY 2024 PDS; this project is not a new start in FY 2025. The most recent DOE Order 413.3B approved Critical Decision (CD) is CD-0, Approve Mission Need, which was approved on April 29, 2021. The project is working to achieve CD-1/3A, Approve Alternative Selection and Cost Range, planned for FY 2024.

Other Project Cost (OPC) activities related to conceptual design and research and development come to completion in FY 2024; the Inflation Reduction Act (IRA) and FY 2023 Enacted Appropriation fully funded activities which will finalize the conceptual design of the facility, modular hot cell units, and radiochemical equipment in preparation for CD-1/3A. The IRA support avoided reallocation of dedicated project staff, reduced project risks, and enabled early value engineering. TEC funding in FY 2025 will support the highest priority engineering design activities related to the facility design and the modular hot cell units.

A Federal Project Director (FPD) with certification Level I has been assigned to RPF.

Critical Milestone History

Fiscal Year	CD-0	Conceptual Design Complete	CD-1	CD-2	Final Design Complete	CD-3	CD-4
FY 2025	4/29/21	3Q FY 2024	3Q FY 2024	4Q FY 2027	TBD	4Q FY 2027	4Q FY 2034

CD-0 – Approve Mission Need for a construction project with a conceptual scope and cost range; **Conceptual Design Complete** – Actual date the conceptual design was completed (if applicable); **CD-1** – Approve Alternative Selection and Cost Range; **CD-2** – Approve Performance Baseline; **Final Design Complete** – Estimated/Actual date the project design will be/was complete(d); **CD-3** – Approve Start of Construction; **D&D Complete** – Completion of D&D work; **CD-4** – Approve Start of Operations or Project Closeout.

Fiscal Year	Performance Baseline Validation	CD-3A	CD-3B
FY 2025	4Q FY 2027	3Q FY 2024	N/A

CD-3A – Approve Long-Lead Procurements (Modular Hot Cell Units and related equipment)

Project Cost History

This project has a pre-CD-1 preliminary point estimate of \$425,300,000 and a CD-0 approved Total Project Cost (TPC) range of \$310,000,000 to \$615,000,000. The table below reflects the upper cost of the TPC range as there is not yet a baseline. No construction, excluding approved long-lead procurement, will be performed until the project performance baseline has been validated and CD-3 has been approved.

(dollars in thousands)

Fiscal Year	TEC, Design	TEC, Construction	TEC, Total	OPC, Except D&D	OPC, Total	TPC
FY 2024	48,500	536,500	585,000	30,000	30,000	615,000
FY 2025	38,300	536,700	575,000	40,000	40,000	615,000

Notes:

- *This project has not received CD-2 approval; therefore, funding estimates are preliminary.*
- *Since project is at CD-0, the funding estimates correlate to the upper end of the estimated TPC range.*

2. Project Scope and Justification

Scope

The scope of this project includes design and construction of a new Hazard Category 2 radioisotope processing facility, approximately 60,000 square feet, and the specialized equipment for chemically processing radioisotopes, with particular focus on irradiated reactor targets. RPF will be a purely technical facility (i.e., minimal office and staff amenities), and located on the Oak Ridge National Laboratory (ORNL) main campus. The design is planned to support up to eight new radioisotope production lines and be equipped with sufficient hot cells grouped to support these new product lines and research. Facility design concepts will include separate bays needed to support reconfigurable heavy shielding for transloading of irradiated targets and waste handling and storage of radioactive materials. The facility will be designed to incorporate other operations required to successfully produce isotopes such as staging and repair of manipulators and other equipment as well as the supporting infrastructure necessary for efficient operations such as cranes to assist in moving casks within the facility. The facility design will address how current Good Manufacturing Practices (cGMP) compliance will be assured. Construction of the proposed facility will also integrate “safety by design”, “quality by design”, and “safeguards by design” standards to ensure safe and efficient future operations.

Justification

RPF is critical to the Nation and to the DOE Isotope Program (DOE IP) within SC’s Office of Isotope R&D and Production. Radioisotopes are commodities essential for energy, medical, space, environmental, and national security applications and for basic research. Currently, radioisotope chemical processing capacity at appropriate hazard category facilities, and outfitted with specialized equipment such as hot cells, glove boxes and supporting laboratories, is the limiting factor for increasing domestic radioisotope production and establishing U.S. independence from foreign supplies of reactor produced isotopes. Without additional radiochemical processing capabilities for isotope separations, especially in proximity to the HFIR at Oak Ridge National Lab, the United States will remain dependent on isotope supply chains from geopolitically sensitive countries such as Russia, putting high priority applications critical to industry, scientific and technical strength, medicine, and national security at risk. RPF will provide radioisotope chemical processing capacity to meet the near-and long-term needs of the nation, therefore promoting U.S. economic growth and resilience, as well as reducing dependence on foreign supply.

The project is being conducted in accordance with the project management requirements in DOE Order 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, and all appropriate project management requirements will be met.

Key Performance Parameters (KPPs)

Preliminary Key Performance Parameters (KPPs) are defined at CD-1 and may change as each subproject continues towards

CD-2, Approve Performance Baseline. CD-1 approval is expected later in 2024. At CD-2 approval, the KPPs will be baselined. The Threshold KPPs represent the minimum acceptable performance that the project must achieve. The Objective KPPs represent the desired project performance. Achievement of the Threshold KPPs will be a prerequisite for approval of CD-4, Project Completion.

Performance Measure	Threshold	Objective
Design/construct building	TBD	TBD
Instrumentation design/development	TBD	TBD

3. Financial Schedule

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Total Estimated Cost (TEC)			
Design (TEC)			
FY 2024	8,500	8,500	8,500
FY 2025	2,000	2,000	2,000
Outyears	27,800	27,800	27,800
Total, Design (TEC)	38,300	38,300	38,300
Construction (TEC)			
Outyears	536,700	536,700	536,700
Total, Construction (TEC)	536,700	536,700	536,700
Total Estimated Cost (TEC)			
FY 2024	8,500	8,500	8,500
FY 2025	2,000	2,000	2,000
Outyears	564,500	564,500	564,500
Total, Total Estimated Cost (TEC)	575,000	575,000	575,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Other Project Cost (OPC)				
Prior Years	3,594	3,594	2,557	–
Prior Years - IRA Supp.	10,600	10,600	–	–
FY 2023	1,000	1,000	893	5,419
FY 2024	–	–	961	3,842
FY 2025	–	–	183	1,339
Outyears	24,806	24,806	24,806	–
Total, Other Project Cost (OPC)	40,000	40,000	29,400	10,600

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Total Project Cost (TPC)				
Prior Years	3,594	3,594	2,557	–
Prior Years - IRA Supp.	10,600	10,600	–	–
FY 2023	1,000	1,000	893	5,419
FY 2024	8,500	8,500	9,461	3,842
FY 2025	2,000	2,000	2,183	1,339
Outyears	589,306	589,306	589,306	–
Total, TPC	615,000	615,000	604,400	10,600

Note:

- Since project is still at CD-0, the funding estimates in the tables above correlate to the upper end of the estimated TPC range.

4. Details of Project Cost Estimate

(dollars in thousands)

	Current Total Estimate	Previous Total Estimate	Original Validated Baseline
Total Estimated Cost (TEC)			
Design	27,000	35,000	N/A
Design - Contingency	11,300	13,500	N/A
Total, Design (TEC)	38,300	48,500	N/A
Construction	370,000	360,000	N/A
Construction - Contingency	166,700	176,500	N/A
Total, Construction (TEC)	536,700	536,500	N/A
Total, TEC	575,000	585,000	N/A
<i>Contingency, TEC</i>	<i>178,000</i>	<i>190,000</i>	<i>N/A</i>
Other Project Cost (OPC)			
Conceptual Design	12,194	12,194	N/A
Start-up	17,806	9,306	N/A
OPC - Contingency	10,000	8,500	N/A
Total, Except D&D (OPC)	40,000	30,000	N/A
Total, OPC	40,000	30,000	N/A
<i>Contingency, OPC</i>	<i>10,000</i>	<i>8,500</i>	<i>N/A</i>
Total, TPC	615,000	615,000	N/A
Total, Contingency (TEC+OPC)	188,000	198,500	N/A

Note:

- Since project is at CD-0, the funding estimates correlate to the upper end of the estimated TPC range.

5. Schedule of Appropriations Requests

(dollars in thousands)

Fiscal Year	Type	Prior Years	FY 2023	FY 2024	FY 2025	Outyears	Total
FY 2024	TEC	—	—	8,500	—	576,500	585,000
	OPC	14,194	1,000	—	—	14,806	30,000
	TPC	14,194	1,000	8,500	—	591,306	615,000
FY 2025	TEC	—	—	8,500	2,000	564,500	575,000
	OPC	14,194	1,000	—	—	24,806	40,000
	TPC	14,194	1,000	8,500	2,000	589,306	615,000

6. Related Operations and Maintenance Funding Requirements

Start of Operation or Beneficial Occupancy	4Q FY 2034
Expected Useful Life	—
Expected Future Start of D&D of this capital asset	—

Related Funding Requirements
(dollars in thousands)

	Annual Costs		Life Cycle Costs	
	Previous Total Estimate	Current Total Estimate	Previous Total Estimate	Current Total Estimate
Operations	N/A	TBD	N/A	TBD
Utilities	N/A	TBD	N/A	TBD
Maintenance and Repair	N/A	TBD	N/A	TBD
Total, Operations and Maintenance	N/A	TBD	N/A	TBD

7. D&D Information

	Square Feet
New area being constructed by this project at ORNL	~60,000
Area of existing facility(ies) being replaced.....	0
Area of any additional D&D space to meet the “one-for-one” requirement.....	0

8. Acquisition Approach

The ORNL Management and Operating (M&O) contractor, UT Battelle, will perform the acquisition for this project, overseen by the DOE Oak Ridge National Laboratory Site Office. The M&O contractor will consider various acquisition approaches and project delivery methods prior to achieving CD-1 and will be responsible for awarding and administering all subcontracts related to this project. Its annual performance evaluation and measurement plan will include project performance metrics on which it will be evaluated.

**24-SC-92, Clinical Alpha Radionuclide Producer (CARP)
Brookhaven National Laboratory, BNL
Project is for Design and Construction**

1. Summary, Significant Changes, and Schedule and Cost History

Summary

The FY 2025 Request for the 24-SC-92, Clinical Alpha Radionuclide Producer (CARP) facility is \$2,000,000, including \$1,000,000 of Total Estimated Cost (TEC) funding and \$1,000,000 of Other Project Costs (OPC) funding. The current Total Project Cost (TPC) pre-conceptual point estimate is \$74,000,000 with CD-0 approved TPC range of \$60,000,000 to \$80,000,000.

Significant Changes

This project data sheet (PDS) is an update of the FY 2024 PDS; this project is not a new start in FY 2025. The most recent DOE Order 413.3B approved Critical Decision (CD) is CD-0, Approve Mission Need, which was approved on December 5, 2022. In FY 2025, OPC funding will continue conceptual design activities for both the facility modification as well as the hot cell and radiochemical equipment conceptual design. In FY 2025, TEC funding will support preliminary design activities for both the facility and the hot cell and radiochemical equipment.

A Federal Project Director (FPD) with certification Level II has been assigned to the BNL CARP.

Critical Milestone History

Fiscal Year	CD-0	Conceptual Design Complete	CD-1	CD-2	Final Design Complete	CD-3	CD-4
FY 2025	12/5/22	TBD	4Q FY 2026	4Q FY 2027	TBD	4Q FY 2027	4Q FY 2031

CD-0 – Approve Mission Need for a construction project with a conceptual scope and cost range; **Conceptual Design Complete** – Actual date the conceptual design was completed (if applicable); **CD-1** – Approve Alternative Selection and Cost Range; **CD-2** – Approve Performance Baseline; **Final Design Complete** – Estimated/Actual date the project design will be/was complete(d); **CD-3** – Approve Start of Construction; **D&D Complete** – Completion of D&D work; **CD-4** – Approve Start of Operations or Project Closeout.

Fiscal Year	Performance Baseline Validation	CD-3A	CD-3B
FY 2025	4Q FY 2027	4Q FY 2026	N/A

CD-3A – Approve Long-Lead Procurements (Facility Utility Infrastructure Equipment)

Project Cost History

The table below reflects the upper cost of the TPC range as there is not yet a baseline. No construction, excluding approved long-lead procurement, will be performed until the project performance baseline has been validated and CD-3 has been approved.

(dollars in thousands)

Fiscal Year	TEC, Design	TEC, Construction	TEC, Total	OPC, Except D&D	OPC, Total	TPC
FY 2024	6,500	63,500	70,000	10,000	10,000	80,000
FY 2025	6,000	64,000	70,000	10,000	10,000	80,000

2. Project Scope and Justification

Scope

The scope of this project includes design and construction activities to retrofit an already existing 7,000 square feet uncontaminated building at Brookhaven National Lab (BNL) that was designed and once operated as a Hazard Category 3 facility, as well as the associated instrumentation and equipment. The proposed facility will be equipped with hot cells, glove boxes, and equipment sufficient in number, space, and capability to support processing of irradiated accelerator targets, as well as Quality Assurance/Quality Control (QA/QC) and shipping and distribution activities. The facility design will address how current Good Manufacturing Practices (cGMP) compliance will be assured. The proposed modifications will also integrate safety, quality, and safeguards standards to ensure safe and efficient future operations.

Justification

CARP, a facility to increase the availability of innovative medical isotopes to diagnose and treat cancer, is essential to the Nation and to the DOE Isotope Program (DOE IP) within SC's Office of Isotope R&D and Production. This facility will enable radiochemistry capabilities to better meet U.S. demand, especially for medical isotopes, and mitigate supply chain interruptions for critical radioisotopes. Radioisotope processing needs to be performed in facilities that carry a Hazard Category designation. The nuclear facility hazard category defines the maximum quantity and type of radioactive material that can be present within a facility. This facility will allow radioisotope processing operations up to and including the Hazard Category 3 level, resulting in significant increases on the amount of material that can be processed, larger batch sizes, and more concurrent processing activities. Isotope production and processing at one of the DOE IP radioisotope production flagship facilities, the Brookhaven Linac Isotope Producer (BLIP), will benefit significantly and allow DOE IP to meet the anticipated demand for radioisotopes for research, medical therapy and diagnosis, commercial applications, and national security, therefore promoting U.S. economic growth and stability. The ability of BLIP to continue to process its irradiated targets will also help decrease U.S. dependence for radioisotopes on other countries, such as Russia.

The project is being conducted in accordance with the project management requirements in DOE Order 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, and all appropriate project management requirements will be met.

Key Performance Parameters (KPPs)

Preliminary Key Performance Parameters (KPPs) are defined at CD-1 and may change as the project continues towards CD-2, Approve Performance Baseline. CD-1 approval is expected in 2026. At CD-2 approval, the KPPs will be baselined. The Threshold KPPs represent the minimum acceptable performance that the project must achieve. The Objective KPPs represent the desired project performance. Achievement of the Threshold KPPs will be a prerequisite for approval of CD-4, Project Completion.

Performance Measure	Threshold	Objective
Design/construct building	TBD	TBD
Instrumentation design/development	TBD	TBD

3. Financial Schedule

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Total Estimated Cost (TEC)			
Design (TEC)			
FY 2024	1,000	1,000	1,000
FY 2025	1,000	1,000	1,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Total Estimated Cost (TEC)			
Outyears	4,000	4,000	4,000
Total, Design (TEC)	6,000	6,000	6,000
Construction (TEC)			
Outyears	64,000	64,000	64,000
Total, Construction (TEC)	64,000	64,000	64,000
Total Estimated Cost (TEC)			
FY 2024	1,000	1,000	1,000
FY 2025	1,000	1,000	1,000
Outyears	68,000	68,000	68,000
Total, Total Estimated Cost (TEC)	70,000	70,000	70,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Other Project Cost (OPC)			
FY 2023	585	585	84
FY 2024	1,500	1,500	2,001
FY 2025	1,000	1,000	1,000
Outyears	6,915	6,915	6,915
Total, Other Project Cost (OPC)	10,000	10,000	10,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Total Project Cost (TPC)			
FY 2023	585	585	84
FY 2024	2,500	2,500	3,001
FY 2025	2,000	2,000	2,000
Outyears	74,915	74,915	74,915
Total, TPC	80,000	80,000	80,000

4. Details of Project Cost Estimate

(dollars in thousands)

	Current Total Estimate	Previous Total Estimate	Original Validated Baseline
Total Estimated Cost (TEC)			
Design	4,000	4,500	N/A
Design - Contingency	2,000	2,000	N/A
Total, Design (TEC)	6,000	6,500	N/A
Construction	43,000	42,500	N/A
Construction - Contingency	21,000	21,000	N/A
Total, Construction (TEC)	64,000	63,500	N/A
Total, TEC	70,000	70,000	N/A
<i>Contingency, TEC</i>	<i>23,000</i>	<i>23,000</i>	<i>N/A</i>
Other Project Cost (OPC)			
Conceptual Design	4,000	4,000	N/A
Start-up	3,000	3,000	N/A
OPC - Contingency	3,000	3,000	N/A
Total, Except D&D (OPC)	10,000	10,000	N/A
Total, OPC	10,000	10,000	N/A
<i>Contingency, OPC</i>	<i>3,000</i>	<i>3,000</i>	<i>N/A</i>
Total, TPC	80,000	80,000	N/A
Total, Contingency (TEC+OPC)	26,000	26,000	N/A

5. Schedule of Appropriations Requests

(dollars in thousands)

Fiscal Year	Type	Prior Years	FY 2023	FY 2024	FY 2025	Outyears	Total
FY 2024	TEC	—	—	1,000	—	69,000	70,000
	OPC	—	—	1,500	—	8,500	10,000
	TPC	—	—	2,500	—	77,500	80,000
FY 2025	TEC	—	—	1,000	1,000	68,000	70,000
	OPC	—	585	1,500	1,000	6,915	10,000
	TPC	—	585	2,500	2,000	74,915	80,000

6. Related Operations and Maintenance Funding Requirements

Start of Operation or Beneficial Occupancy	4Q FY 2031
Expected Useful Life	—
Expected Future Start of D&D of this capital asset	—

Related Funding Requirements
(dollars in thousands)

	Annual Costs		Life Cycle Costs	
	Previous Total Estimate	Current Total Estimate	Previous Total Estimate	Current Total Estimate
Operations	TBD	TBD	TBD	TBD
Utilities	TBD	TBD	TBD	TBD
Maintenance and Repair	TBD	TBD	TBD	TBD
Total, Operations and Maintenance	TBD	TBD	TBD	TBD

7. D&D Information

The new area being constructed in this project is not replacing existing facilities.

	Square Feet
New area being constructed by this project at BNL.....	N/A
Area of D&D in this project at BNL.....	N/A
Area at BNL to be transferred, sold, and/or D&D outside the project, including area previously "banked"	N/A
Area of D&D in this project at other sites	N/A
Area at other sites to be transferred, sold, and/or D&D outside the project, including area previously "banked"	N/A
Total area eliminated	N/A

8. Acquisition Approach

The BNL Management and Operating (M&O) contractor, Brookhaven Science Associates, will perform the acquisition for this project, overseen by the DOE Brookhaven National Laboratory Site Office. The M&O contractor will consider various acquisition approaches and project delivery methods prior to achieving CD-1 and will be responsible for awarding and administering all subcontracts related to this project. Its annual performance evaluation and measurement plan will include project performance metrics on which it will be evaluated.

**20-SC-51, U.S. Stable Isotope Production and Research Center (SIPRC)
Oak Ridge National Laboratory, ORNL
Project is for Design and Construction**

1. Summary, Significant Changes, and Schedule and Cost History

Summary

The FY 2025 Request for the U.S. Stable Isotope Production and Research Center (SIPRC) is \$45,900,000 of Total Estimated Cost (TEC) funding. The current Total Project Cost (TPC) point estimate is \$325,000,000 with a preliminary TPC range of \$187,000,000 to \$338,000,000.

Significant Changes

This project data sheet (PDS) is an update of the FY 2024 PDS; the project is not a new start in FY 2025. The most recent DOE Order 413.3B approved Critical Decisions (CD) are CD-1, “Approve Alternative Selection and Cost Range” and Subproject 1 (SP-1) CD-3B, “Approve Long-Lead Procurements”, which was approved on July 19, 2023, as a risk mitigation strategy due to significant increases in lead times for critical EMIS magnet components. SIPRC is not baselined but the approval of CD-2/3, Approve Performance Baseline and Approve Start of Construction for SIPRC SP-1, is anticipated in the first half of FY 2024 that will authorize the start of SP-1 Construction-related activities.

The Inflation Reduction Act (IRA) funding received in FY 2022 optimized project performance through FY 2024 and will be expended by early FY 2025. The FY 2025 Request will continue support for construction activities that include completing funding for the phased conventional construction award as well as the procurement of equipment based on known designs of technologies developed under previous efforts. FY 2025 PED funding will support the completion of design activities related to the gas centrifuge scope as Subprojects 2 and 3 prepare for CD-2/3.

The shift in schedule reflects impacts from construction-related supply chain challenges and advancing project maturity through preliminary engineering design.

The KPP’s of SP-1 have been adjusted to enable phased implementation of EMIS units as they are completed.

A Federal Project Director (FPD) with certification Level III has been assigned to the SIPRC.

Critical Milestone History

	CD-0	Conceptual Design Complete	CD-1	CD-2	Final Design Complete	CD-3	CD-4
SIPRC Project	1/4/19	2/26/21	11/4/21	4Q FY 2026	4Q FY 2026	4Q FY 2026	3Q FY2032
SIPRC SP-1 - Facility and EMIS	1/4/19	2/26/21	11/4/21	1Q FY 2024	1Q FY 2024	2Q FY 2024	4Q FY2030
SIPRC SP-2 - Mo-100 Cascade	1/4/19	2/26/21	11/4/21	4Q FY 2026	4Q FY 2026	4Q FY 2026	3Q FY 2032
SIPRC SP-3 - Test Cascade Infrastructure	1/4/19	2/26/21	11/4/21	4Q FY 2026	4Q FY 2026	4Q FY 2026	2Q FY 2032

Notes:

- Dates shown in the SIPRC Project row in table above correspond to the latest subproject date (broken out by subproject in rows below).
- The estimated schedules shown are preliminary.

CD-0 – Approve Mission Need for a construction project with a conceptual scope and cost range; **Conceptual Design Complete** – Actual date the conceptual design was completed (if applicable); **CD-1** – Approve Alternative Selection and Cost Range; **CD-2** – Approve Performance Baseline; **Final Design Complete** – Estimated/Actual date the project design will be/was complete(d); **CD-3** – Approve Start of Construction; **D&D Complete** – Completion of D&D work; **CD-4** – Approve Start of Operations or Project Closeout.

	Performance Baseline Validation	CD-3A	CD-3B
SIPRC Project	4Q FY 2026	11/4/21	7/19/23
SIPRC SP-1 - Facility and EMIS	1Q FY 2024	11/4/21	7/19/23
SIPRC SP-2 - Mo-100 Cascade	4Q FY 2026	1Q FY 2026	N/A
SIPRC SP-3 - Test Cascade Infrastructure	4Q FY 2026	1Q FY 2026	N/A

Note:

- Dates shown in the SIPRC Project row in table above correspond to the latest subproject date (broken out by subproject below). Dates shown for CD-3C are anticipated.

CD-3A for Subproject 1 – Approve Long-Lead Procurements (EMIS components and Facility Site Preparation)

CD-3B for Subproject 1 – Approve Long-Lead Procurements (Additional EMIS components)

CD-3A for Subproject 2 – Approve Long-Lead Procurements (Additional GC components)

CD-3A for Subproject 3 – Approve Long-Lead Procurements (Additional GC components)

Project Cost History

This project is at CD-1/3A with a preliminary point estimate of \$325,000,000 and Total Project Cost (TPC) range of \$187,000,000 to \$338,000,000. No construction, excluding for approved long-lead procurement, will be performed until the project performance baseline has been validated and CD-3 has been approved.

(dollars in thousands)

Fiscal Year	TEC, Design	TEC, Construction	TEC, Total	OPC, Except D&D	OPC, Total	TPC
FY 2024	36,000	276,800	312,800	12,200	12,200	325,000
FY 2025	31,000	282,800	313,800	11,200	11,200	325,000

2. Project Scope and Justification

Scope

The scope of this project includes design and construction of a building, approximately 64,000 square feet, and associated instrumentation and equipment for enriching isotopes. Electromagnetic isotope separator systems and gas centrifuge cascades will be designed and installed in this new facility to promote operational, cost and security effectiveness, with space for future growth. The planned facility will include adequate space for test stands and prototype systems development and will be a purely technical facility (i.e., minimal office and staff amenities), and located on the Oak Ridge National Laboratory (ORNL) main campus. Gas centrifuges and electromagnetic separators are based on existing designs leveraging prior projects and R&D supported by the DOE Isotope Program (DOE IP). The laboratory considered the optimal number of production systems for each type of technology as part of the alternatives analysis for CD-1.

Justification

SIPRC is essential to the Nation and to the DOE Isotope Program (DOE IP) within SC’s Office of Isotope R&D and Production. The facility will expand the only broad U.S. stable isotope production capability to enable multiple production campaigns of enriched stable isotopes. SIPRC will use innovative technology to establish domestic supply chains of critical stable isotopes and nurture domestic core competencies in enrichment technologies using centrifuges and electromagnetic ion separators. This will provide domestic supply chains of critical isotopes for industry, medicine, and national security and mitigate U.S. dependencies on foreign suppliers, a critical need which has been magnified by the Russian invasion of Ukraine and the development of a stable isotope production facility in China. The current capacity within the U.S. is insufficient to meet the Nation’s growing demands and the current inventory of stable isotopes is being depleted. The SIPRC project will provide an adequately sized building and transformative technology to address our Nation’s stable isotope needs in a more economical and operationally efficient manner.

The project is being conducted in accordance with the project management requirements in DOE Order 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, and all appropriate project management requirements will be met.

Key Performance Parameters (KPPs)

Preliminary Key Performance Parameters (KPPs) are defined at CD-1 and may change as each subproject continues towards CD-2, Approve Performance Baseline. CD-1 approval was received November 4, 2021. At CD-2 approval, the KPPs will be baselined. The Threshold KPPs represent the minimum acceptable performance that the project must achieve. The Objective KPPs represent the desired project performance. Achievement of the Threshold KPPs will be a prerequisite for approval of CD-4, Project Completion.

Summary of preliminary KPPs is indicated below.

Performance Measure	Threshold	Objective
Design/construct building	SP-1 – Facility and EMIS: Beneficial occupancy of the facility obtained.	SP-1 – Facility and EMIS: Beneficial occupancy of the facility obtained.
Instrumentation design/development	SP-1 – Facility and EMIS: Ninety percent (90 percent) of the EMIS machines complete a functional operability demonstration of individual EMIS machines running with gas for 4 hours.	SP-1 – Facility and EMIS: One hundred percent (100 percent) of the EMIS machines complete a functional operability demonstration of individual EMIS machines running with gas for 4 hours.
	SP-2 – Mo-100 Cascade: a. The SIPRC project will complete the validation and verification (V&V) of the controls system with the completed documentation of the process. b. The SIPRC project will complete documented system leak tests with results meeting the requirements laid out in the systems requirements documents. c. The SIPRC project will complete a mechanical operability test of the completed production GCIS cascade.	SP-2 – Mo-100 Cascade: The SIPRC project will complete a 100Mo gas test of the constructed cascade using molybdenum hexafluoride gas. Evidence of completion will be the report on the results of the gas test.

Performance Measure	Threshold	Objective
	SP-3 – Test Cascade Infrastructure: a. The SIPRC project will complete the V&V of the controls system with the completed documentation of the process. b. The SIPRC project will complete documented system leak tests with results meeting the requirements laid out in the systems requirements documents.	SP-3 – Test Cascade Infrastructure: The SIPRC project will successfully complete an operability test of the TCI’s feed and withdrawal system using a defined gas. The system must be able to flow gas at the planned flow rate range per the systems requirements document and withdraw the gas from the system piping into cold traps. Evidence of completion will be a report on the results of this test.

3. Financial Schedule

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Total Estimated Cost (TEC)				
Design (TEC)				
Prior Years	21,000	21,000	6,033	—
FY 2023	6,000	6,000	5,673	—
FY 2024	—	—	1,000	—
FY 2025	4,000	4,000	—	—
Outyears	—	—	18,294	—
Total, Design (TEC)	31,000	31,000	31,000	—
Construction (TEC)				
Prior Years	15,000	15,000	—	—
Prior Years - IRA Supp.	75,000	75,000	—	—
FY 2023	18,000	18,000	9,977	—
FY 2024	20,900	20,900	7,000	75,000
FY 2025	41,900	41,900	45,023	—
Outyears	112,000	112,000	145,800	—
Total, Construction (TEC)	282,800	282,800	207,800	75,000
Total Estimated Cost (TEC)				
Prior Years	36,000	36,000	6,033	—
Prior Years - IRA Supp.	75,000	75,000	—	—
FY 2023	24,000	24,000	15,650	—
FY 2024	20,900	20,900	8,000	75,000
FY 2025	45,900	45,900	45,023	—
Outyears	112,000	112,000	164,094	—

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Total Estimated Cost (TEC)				
Total, Total Estimated Cost (TEC)	313,800	313,800	238,800	75,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Other Project Cost (OPC)			
Prior Years	8,800	8,800	3,435
FY 2023	–	–	1,465
FY 2024	–	–	2,535
Outyears	2,400	2,400	3,765
Total, Other Project Cost (OPC)	11,200	11,200	11,200

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Total Project Cost (TPC)				
Prior Years	44,800	44,800	9,468	–
Prior Years - IRA Supp.	75,000	75,000	–	–
FY 2023	24,000	24,000	17,115	–
FY 2024	20,900	20,900	10,535	75,000
FY 2025	45,900	45,900	45,023	–
Outyears	114,400	114,400	167,859	–
Total, TPC	325,000	325,000	250,000	75,000

4. Details of Project Cost Estimate

(dollars in thousands)

	Current Total Estimate	Previous Total Estimate	Original Validated Baseline
Total Estimated Cost (TEC)			
Design	25,000	30,000	N/A
Design - Contingency	6,000	6,000	N/A
Total, Design (TEC)	31,000	36,000	N/A

(dollars in thousands)

	Current Total Estimate	Previous Total Estimate	Original Validated Baseline
Construction	232,000	200,000	N/A
Construction - Contingency	50,800	76,800	N/A
Total, Construction (TEC)	282,800	276,800	N/A
Total, TEC	313,800	312,800	N/A
<i>Contingency, TEC</i>	<i>56,800</i>	<i>82,800</i>	<i>N/A</i>
Other Project Cost (OPC)			
Conceptual Design	8,800	8,000	N/A
Start-up	1,500	2,500	N/A
OPC - Contingency	900	1,700	N/A
Total, Except D&D (OPC)	11,200	12,200	N/A
Total, OPC	11,200	12,200	N/A
<i>Contingency, OPC</i>	<i>900</i>	<i>1,700</i>	<i>N/A</i>
Total, TPC	325,000	325,000	N/A
Total, Contingency (TEC+OPC)	57,700	84,500	N/A

5. Schedule of Appropriations Requests^a

(dollars in thousands)

Fiscal Year	Type	Prior Years	FY 2023	FY 2024	FY 2025	Outyears	Total
FY 2024	TEC	111,000	24,000	20,900	—	156,900	312,800
	OPC	8,800	—	—	—	3,400	12,200
	TPC	119,800	24,000	20,900	—	160,300	325,000
FY 2025	TEC	111,000	24,000	20,900	45,900	112,000	313,800
	OPC	8,800	—	—	—	2,400	11,200
	TPC	119,800	24,000	20,900	45,900	114,400	325,000

6. Related Operations and Maintenance Funding Requirements

Start of Operation or Beneficial Occupancy	3Q FY2032
Expected Useful Life	30 years
Expected Future Start of D&D of this capital asset	3Q FY2062

Note:

- *Start of Operations reflects the initiation of phased implementation of operations for the EMIS units.*

^a The project does not have CD-2 approval; FY 2025 schedules and costs are estimates consistent with the updated preliminary point estimate.

Related Funding Requirements
(dollars in thousands)

	Annual Costs		Life Cycle Costs	
	Previous Total Estimate	Current Total Estimate	Previous Total Estimate	Current Total Estimate
Operations	33,295	33,295	1,106,807	1,106,807
Utilities	4,053	4,053	133,735	133,735
Maintenance and Repair	2,992	2,992	90,458	90,458
Total, Operations and Maintenance	40,340	40,340	1,331,000	1,331,000

Note:

- Life Cycle Costs includes escalation.

7. D&D Information

	Square Feet
New area being constructed by this project at ORNL	64,000
Area of existing facility(ies) being replaced	0
Area of any additional D&D space to meet the “one-for-one” requirement	0

The new area being constructed in this project is not replacing existing facilities. Any existing space that is freed up from consolidating activities into SIPRC will likely be repurposed.

8. Acquisition Approach

The ORNL Management and Operating (M&O) contractor, UT Battelle, will perform the acquisition for this project, overseen by the DOE Oak Ridge National Laboratory Site Office. The M&O contractor will be responsible for awarding and administering all subcontracts related to this project. Its annual performance evaluation and measurement plan will include project performance metrics on which it will be evaluated.

Isotope Production and Distribution Program Fund

Overview

The Department of Energy's (DOE) Isotope Production and Distribution Program Fund provides a revolving account for the DOE Isotope Program (DOE IP) to enable the production of critical isotopes in short supply to the Nation and develops robust domestic supply chains to meet federal missions, facilitates emerging technology, and promotes the Nation's economic prosperity and technical competitiveness. The DOE IP produces and sells radioactive and stable isotopes, byproducts, surplus materials, and related isotope services worldwide to federal agencies, universities, and industry. One of the DOE IP's priorities is to mitigate the Nation's dependency on isotope supply chains from geopolitically sensitive countries. The National Isotope Development Center (NIDC) manages contractual obligations with customers, marketing, and isotope production coordination.

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. The Isotope Production and Distribution Program Fund was established by the 1990 Energy and Water Development Appropriations Act (Public Law 101-101) and amended by the 1995 Energy and Water Development Appropriations Act (Public Law 103-316). Funding for this revolving fund is provided by the annual appropriations from the Science appropriation account (through the Office of Isotope R&D and Production Program [IRP or DOE IP]) and collections from isotope sales; both are needed to maintain the supplies of critical isotopes. 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 does not become cost prohibitive. The revolving fund allows continuous and smooth operations of isotope production, sales, and distribution independent of the federal budget cycle and fluctuating sales revenue. It also enables the DOE IP to operate during times of national crisis, such as COVID-19 and the Russian invasion of Ukraine. An external contractor conducts an independent cost review of the fund's revenues and expenses annually.

Annual appropriations in the DOE IP program support payments into the revolving fund to maintain mission-readiness of facilities, including the support of core scientists and engineers need to produce and process isotopes, and the maintenance and enhancement of isotope facilities and capabilities to ensure 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. Appropriated funding also supports infrastructure refurbishment and enhancements in capabilities to quickly respond to isotope supply chain disruptions, as well as construction funds for ongoing line-item projects. Customer revenues offset the costs of producing, dispensing, packaging, and shipping isotopes; these revenues are also deposited into the revolving fund. About 90 percent of the total resources in the revolving fund are used for operations, maintenance, isotope production, and R&D for new isotope production techniques, with approximately 10 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.

In FY 2024, an estimated total of \$237.4 million will be deposited into the revolving fund. This consists of the FY 2024 President's Budget Request of \$173 million that will be paid into the revolving fund from the Isotope R&D and Production program, plus anticipated collections by NIDC of \$64.4 million to recover costs related to isotope production and isotope services. In FY 2024, the DOE IP expects to sell over 125 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.

Highlights of the FY 2025 Request

In FY 2025, 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, including fusion energy; and isotopes for nuclear batteries, semiconductor manufacturing, and power supplies. The Program continues to focus on developing U.S. independence from Russian isotope supply chains and enabling the DOE IP to be proactive and target high-risk supply chains effectively to ensure that the U.S. has access to isotopes for discovery science, essential industrial applications, Administration priorities, and to combat cancer.

The DOE IP program's FY 2025 Request is \$183.9 million, an increase of \$74.4 million over FY 2023 Enacted. In FY 2025, we also anticipate additional collections by NIDC to recover costs related to isotope production and isotope services. Revolving fund resources will be used to address the following priorities in the program:

- Promote world-leading core competencies for isotope production to address gaps in supply chains and the provision of innovative, rare isotopes for high priority applications.
- Support facilities with a high degree of mission readiness so that they can operate safely, reliably, and efficiently to respond to crisis situations and fill gaps in isotope supply chains.
- Introduce novel and critical isotopes to the Nation through cutting-edge research and advanced manufacturing 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.
- Advance and expand transformative, domestic stable isotope enrichment capabilities.
- Enhance isotope processing capabilities to address a lack of radiochemical processing capacity limiting the availability of new isotopes, mitigating single point failures to increase the Nation's preparedness for reacting to global supply chain disruptions.
- Address targeted, high priority critical equipment needs to increase operational reliability of facilities by addressing single point failures, increasing spare components, and replacing obsolete equipment.

Program Accomplishments

Newly Refurbished Hot Cells Produce Record Batch Size of Rare Cancer Therapeutic

The recently renovated All-Purpose (AP) Hot Cells at Brookhaven National Laboratory (BNL) enabled a record-breaking achievement of the DOE IP Tri-Lab Ac-225 Research Effort, the largest Ac-225 batch to date: 112 mCi of Ac-225 was produced and made available for innovative cancer therapy. Ac-225 shows stunning success in treating metastasized cancers but is in short supply. The Tri-Lab collaboration established reliable, routine Ac-225 production, demonstrating that the process is scalable, but had been constrained at the 50 mCi level due to insufficient radiochemical processing capacity at the target irradiation sites (BNL and Los Alamos National Laboratory [LANL]). The renovation of the AP Hot Cells was completed in 2023, and the BNL Medical Isotope Research and Production Program (MIRP) successfully and reliably produced monthly batches of Ac-225 since operations were authorized. With the AP Hot Cells, DOE can provide additional supply of Ac-225 to support clinical trials.

The DOE IP Welcomes the University of Wisconsin-Madison and Texas A&M to the University Isotope Network (UIN)

The University of Wisconsin-Madison (UWM) Cyclotron Research Group joined the DOE IP UIN for the production of research and "boutique" isotopes. Supported by DOE IP funding, the UWM Cyclotron Research Group developed three new production lines of medical isotopes (Manganese-52g, Bromine-77, and Yttrium-86) and are now in routine production and available through NIDC. The UWM Cyclotron Research group brings expertise in developing targets for isotope production using low energy cyclotrons and will serve as the target resource for the other cyclotrons sites with the UIN. Texas A&M Cyclotron Institute has developed Astatine-211 (At-211) production which is now available for routine regional distribution through NIDC. There are now six universities in the UIN.