

Isotope R&D and Production

Overview

The mission of the DOE Isotope Program (DOE IP) is to:

- Produce and/or distribute stable isotopes and radioisotopes in short supply or unavailable in the U.S., including related isotope services;
- Maintain mission readiness of critical national infrastructure and core competencies needed to manufacture isotopes and ensure national preparedness 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 a diverse and inclusive 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 in short supply for the Nation that no domestic entity has the capability to meet market demand. The Program is typically the only, or one of few, global producers for these rare isotopes; however, the U.S. remains highly dependent on isotope supply chains from sensitive countries. Isotopes are high-priority and 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 needed isotopes for commercial stability and growth, and facilitates commercialization of isotope production to the domestic private sector. DOE IP is the only DOE “Mission Essential Function” in SC and continues operations during national emergencies to mitigate disruptions in isotope supply chains. DOE IP stepped in during the COVID-19 pandemic and Russian invasion of Ukraine to mitigate disruptions in supply chains critical to federal agencies, industry, and research.

The DOE IP utilizes particle accelerators and research nuclear reactors at national laboratories and universities to irradiate targets which are then processed in radiochemical infrastructure to extract radioisotopes of interest; DOE IP also extracts 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; Russia is the other major producer of He-3. The DOE IP is responsible for the national repository of all stable isotopes that were created by the calutrons (electromagnetic ion separation) developed as part of the Manhattan Project. The calutrons ceased operations in 1998, leaving the U.S. with no broad isotope enrichment capability. Russia has the largest stable isotope enrichment capability worldwide and China has recently started operation of a new facility with significant capabilities. The U.S. inventory of stable isotopes is limited, causing the U.S. to rely on foreign countries for critical stable isotopes. The DOE IP is developing 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 underpin many essential aspects of basic and applied nuclear and radiochemical science. Research and production activities develop and employ techniques and platform technologies in artificial intelligence (AI), machine learning (ML), robotics, and advanced manufacturing.

Funds in this Request support mission readiness of infrastructure, staff, and facilities; research; and new capabilities to meet the Nation’s growing demand for isotopes. Customer collections from sales pay for the actual production of the isotope, distribution, and related services. Isotopes sold to commercial customers and foreign entities are priced at full-cost recovery or market price (whichever is higher). Isotope pricing for domestic research is reduced to promote innovation and scientific advances. DOE IP funding is executed through the Isotope Production and Distribution Program revolving fund, where both appropriated funding and customer revenues are deposited and executed for Program viability.

Highlights of the FY 2024 Request

In FY 2024, the DOE IP expects increasing demand in both radio and stable isotopes. The Russian invasion of Ukraine and subsequent impacts to isotope supply chains have highlighted the need for domestic supplies of critical isotopes. Demand of radioisotopes increases for high priority national applications and technologies such as nuclear batteries, power sources, clean energy technologies, semiconductor and microelectronics manufacturing, quantum computing, next generation molten salt and fusion reactors, and medical treatment and diagnosis of cancer and infectious disease.

In FY 2024, support for operations of production facilities increases to 92 percent optimal and supports additional workforce to respond more efficiently as a DOE Mission Essential Function and fill gaps in supply chains. Funding for mission readiness is also provided for the first time to the Pacific Northwest National Laboratory (PNNL), the Y-12 Security Complex, Idaho National Laboratory (INL), and the Los Alamos National Laboratory (LANL) Plutonium facility to improve stable operations. Funding enables the Linear Electron Accelerator Facility (LEAF) at Argonne National Laboratory (ANL) to transition from NNSA to DOE IP for increased production of medical isotopes. A newly refurbished low energy medical cyclotron at Brookhaven National Laboratory (BNL) ramps up to produce actinium-225. Support is provided to address deferred maintenance and single point failures to ensure safe, robust and reliable operations across production sites. Funding supports the receipt and testing of the first heavy curium product stream (for critical radioisotope production) coming from the processing of Mark 18-A legacy reactor targets.

FY 2024 funding enables the standup of a new group in stable isotope enrichment operations to prepare for the start of operations of the Stable Isotope Production Facility (SIPF) Major Item of Equipment and eventually the Stable Isotope Production and Research Center (SIPRC). SIPF will operate the Nation's first full-scale and modern gas centrifuge cascade to produce Xe-129 for polarized lung imaging. Staff assemble and commission new electromagnetic ion separation (EMIS) devices to produce high priority enriched stable isotopes. The Program develops a heavy water inventory, enabled with Inflation Reduction Act (IRA) funding. FY 2024 funding also increases staffing at the National Isotope Development Center (NIDC), the business arm of the DOE IP, to address the increased interfaces with stakeholder community.

The DOE Isotope Initiative will support the conduct of research to proactively address current or looming high-impact isotope shortages. In FY 2024, this initiative focuses on three high priority isotopes that are currently in short supply and otherwise only available from Russia. Krypton-85 is utilized in semiconductor manufacturing and research efforts establish a domestic supply chain to meet federal and U.S. industrial demand. Research develops new chemical separations to restore and increase the Sr-90 inventory to better meet the rising demand for nuclear batteries and medical applications. New techniques are researched and developed to explore unique sources of He-3 and increase the national inventory.

The Reaching a New Energy Sciences Workforce (RENEW) and Funding for the Accelerated, Inclusive Research (FAIR) initiatives expand DOE IP efforts to advance justice, equity, diversity, and inclusion in SC-sponsored research. The DOE IP involvement in the Biopreparedness Research Virtual Environment (BRaVE) initiative increases to enhance national preparedness with investment of equipment and research to produce isotopes at the Radioisotope Science Center (RSC) at the University of Missouri (MURR), creating jobs in an underserved community. New investments in microelectronics supports research to produce isotopes needed for microelectronics fabrication and development. DOE IP continues as part of the Accelerate Innovations in Emerging Technologies initiative. DOE IP will increase support of translational research, in coordination with the NIH, for novel medical isotopes used in medical trials. The DOE IP maintains efforts in the Advanced Manufacturing initiative and QIS to advance the production of isotopes of interest for QIS.

Support increases for the University Isotope Network, providing support for Texas A&M University and the University of Wisconsin-Madison to participate in the network. The Facility for Rare Isotope Beams (FRIB) Isotope Harvesting effort approaches completion, adding capabilities to extract and process rare isotopes from the beam dump of the FRIB.

The FY 2024 Request includes \$20.9 million in Total Estimated Cost (TEC) funding to continue SIPRC, which in combination with the funding provided by the Inflation Reduction Act, positions the project closer to its optimal profile. SIPRC restores large scale stable isotope enrichment capacity for the Nation to remove U.S. dependency on foreign countries. The Request initiates construction for the Radioisotope Processing Facility (RPF) to address a lack of available radiochemical processing infrastructure to mitigate U.S. dependency on foreign supply chains of radioisotopes. Funding supports engineering design and long lead procurements for the Clinical Alpha Radionuclide Producer (CARP) facility 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 2022 Enacted	FY 2023 Enacted	FY 2024 Request	FY 2024 Request vs FY 2023 Enacted
Isotope R&D and Production				
Isotopes, Research	32,133	38,827	63,827	+25,000
Isotopes, Operations	37,867	46,624	78,824	+32,200
Subtotal, Isotope R&D and Production	70,000	85,451	142,651	+57,200
Construction				
20-SC-51 U.S. Stable Isotope Production and Research Center (SIPRC), ORNL	12,000	24,000	20,900	-3,100
24-SC-92 Clinical Alpha Radionuclide Producer (CARP), BNL	—	—	1,000	+1,000
24-SC-91 Radioisotope Processing Facility, ORNL	—	—	8,500	+8,500
Subtotal, Construction	12,000	24,000	30,400	+6,400
Total, Isotope R&D and Production	82,000	109,451	173,051	+63,600

Basic and Applied R&D Coordination

R&D coordination and integration are deeply rooted in all activities of the DOE IP as a goal of the Program is to ensure that critical isotopes are available to achieve federal missions, industrial applications, and support R&D. 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 participates in Federal Working Groups and Interagency groups to promote communication, including the White House Office of Science and Technology Policy (OSTP) National Science and Technology Council (NSTC) Subcommittee on Critical and Strategic Mineral Supply Chains, the Interagency Group on He-3, which it leads, and the OSTP NSTC Subcommittee on Fusion Energy. The DOE IP participates in the Nuclear Sub-Inter Policy Committee (Sub-IPC), Fusion Sub-IPC, Russian Sanctions IPC, White House Small Group on Sterilization and Medical Isotopes, QIS Working Group, and the Certified Reference Material Working Group, which ensures material availability for nuclear forensics applications to support national security missions. Other groups include the NNSA GARS II Working Group and the NRC Radiation Source Protection and Security Task Force. 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, meets throughout the year with industrial stakeholders to gauge the health of global supply chains, including two multiple-day sessions of dedicated meetings. 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 (IRDPAC), 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, the 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

Promoting the Commercialization of a Promising Medical Isotope World-wide

Astatine-211 (At-211) has shown great promise in preclinical and clinical trials as a radioisotope for the treatment of multiple forms of cancer including leukemia, lymphoma, glioblastoma, and ovarian cancers. Because of its short half-life, effective distribution of At-211 is achieved with regional production sites. The DOE IP has been establishing a production network for At-211 across the Nation. The University of Washington Medical Cyclotron Facility (UWMCF) is currently one of five sites within the U.S., and one of a handful globally, with such a capability. To increase the domestic availability of At-211 for research and clinical use, UWMCF engineers designed and fabricated a new target station that could be retrofitted to existing small-medical cyclotrons and a target optimized for At-211 production. The newly fabricated and patented target station is fully automated, significantly improving the efficiency and safety of isotope production, and adaptable for production of other isotopes. The DOE IP is making this technology available world-wide to researchers and industry to promote commercialization of At-211.

Gold-199 (Au-199) Domestic Supply Chain Established for Environmental and Biomedical Research

Gold-199 (Au-199) has drawn interest from the biomedical research community due to its theragnostic potential for targeted radioimmunotherapy, as nanoparticles for biomedical imaging applications, and in radiolabeling for detection of environmental compounds; a theragnostic isotope can be used for both diagnosis and treatment, reducing patient dose.

DOE IP supported the University of Missouri Research Reactor (MURR), a production site within the DOE IP University Isotope Network, to develop a production capability for Au-199. MURR is now being utilized to support nationwide availability of this short-lived radioisotope, establishing a new domestic supply chain for this novel product.

Improving Predictive Power of Modeling Codes for Isotope Production (and spacecraft design)

Researchers from LANL, BNL, and Lawrence Berkeley National Laboratory (LBNL) have formed the Tri-Lab Effort in Nuclear Data, an ongoing DOE IP funded effort to measure the nuclear data needed to inform and optimize production of emerging radionuclides. In FY 2022, the teams measured the production of Lead-202, a rare radionuclide used in geochronology as an environmental tracer and calibration standard for mass spectrometry. The team performed a series of experiments at the BNL Brookhaven Linac Isotope Producer, the LANL Isotope Production Facility, and the LBNL 88-Inch Cyclotron. Production rates for 78 isotopes were measured using proton bombardment of lead, niobium, and arsenic targets with energies up to 200 MeV, including two radionuclides used for Positron Emission Tomography (PET). Comparison of this data to predictions by state-of-the-art nuclear reaction models enabled the study of how quickly the energy from an incoming proton is spread over the entire nucleus. The results show that energy gets distributed in the nucleus more slowly than expected leading to an increase in higher energy particles getting released; this influences the relative production of isotopes with different proton-to-neutron ratios. Using state-of-the-art nuclear reaction modeling codes, the data also allows to better tune the performance of these codes for reactions which have not yet been measured. These results can improve the accuracy of the codes from within a factor of 10-20 to within 5 percent, minimizing the production of contaminants in radiopharmaceuticals for human use, e.g., for PET, and influencing the design of shielding for new generations of spacecraft.

Robotics and Automation Advances Isotope Manufacturing

The radiochemistry team at LANL has deployed the “LANL Super Separator,” enabling automation of radiochemical separation R&D and reducing the time needed to bring crucial radioisotopes to market for the DOE IP. This capability brings robotics to the radiochemistry toolset, which has so far been manual, enabling rapid development and optimization of radioisotope processing and separation methods. This instrument has been used to develop optimized chemical separation methods for new radioisotopes and to optimize existing production lines—through automation and rapid screening of different chemical separation options. The LANL Super Separator has demonstrated significant acceleration of separation optimization. Applied to existing product lines, the instrument enabled quick characterization of the impact from radiolysis versus chemical degradation on resin performance for over 20 potential contaminants and six resins within the confines of current production restrictions. The results are supporting the DOE IP’s efforts to bring new radioisotopes into production this calendar year and the need to maintain and improve the Program’s processing capability.

Creative Partnerships to Optimize Isotope Productivity

Strontium-89 (Sr-89) has demonstrated a significant palliative benefit in the treatment of painful bone cancer metastases, due to the affinity of strontium in the bones. ORNL has historically performed the domestic production of this important radioisotope. With domestic radioisotope production hampered by the lack of radiochemical infrastructure, DOE IP examined whether radiochemical processing facilities were available that could process irradiated Sr-89 targets to free up processing space at ORNL to tackle emerging isotope shortages. ORNL and LANL subsequently partnered to develop and implement Sr-89 radiochemical processing capabilities at LANL. The material is irradiated in HFIR at ORNL and then shipped to LANL. At LANL, the material is chemically purified before being shipped to a customer. This successful partnership is a step forward for increasing the overall supply of Sr-89 and enabled ORNL to ramp up production of barium-133, an isotope used in QIS and industrial radiography, otherwise only produced in Russia.

New Partnership with a University Increases Domestic Supplies of Isotopes

The DOE IP introduced four domestic isotope supply chains to the Nation with the recent entrance of the University of Alabama Birmingham (UAB) into its University Isotope Network (UIN). The UAB cyclotron facility has joined the UIN and will produce a reliable supply of isotopes focused on advancing scientific research, including cobalt-55, manganese-52, vanadium-48, and lead-203. Cobalt-55 shows promising use in PET imaging of cancer and other diseases, lung and oncology imaging, and targeted radiolabeled antibodies for ablation therapy. Manganese-52 is an isotope of interest as a long-lived positron emitter for investigating the biodistribution of intact antibodies or nanoparticles, and as a potential PET analog. Vanadium-48 is of interest as a long-lived positron emitter for the study of vanadium chemistry and biochemistry, nutrition, and as a target isotope for cross-sections of interest for stockpile stewardship. Lead-203 is a diagnostic partner to the therapeutic lead-212 radioisotope, forming a theragnostic radioisotope pair for targeted cancer treatments.

Isotope R&D and Production

Description

Research

Research funding supports core research groups at national laboratories and universities for both stable and radioisotopes, 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. The DOE IP supports core research groups at ANL, BNL, INL, LANL, ORNL, and PNNL to conduct advanced research for novel or advanced production and separation techniques for high priority isotopes in short supply. A priority is to develop a broad national stable isotope enrichment core competency. A stable isotope enrichment core competency is essential for the U.S. as enriched stable isotopes are foundational to so many applications, including the production of all radioisotopes. The production of each enriched stable isotope requires an intense research campaign. Machines are designed and optimized for isotopes of interest for quantum computing as part of the SC QIS Initiative. This technology is dual-use and the Program exploits synergies with NNSA. Stable isotope research to promote clean energy considers isotopically tailored low activation materials for fusion and fast fission nuclear reactors and transformative technology development to enrich isotopes that can yield fuel cycle cost savings and reduced nuclear waste.

Core research support is 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, MURR, FRIB Isotope Harvesting at MSU, University of Alabama-Birmingham (UAB) and University of Wisconsin-Madison (UWM). Texas A&M University is expected to join in the near future. These universities have unique capabilities, such as the UW multi-particle cyclotron, where full-scale production of the alpha-emitter astatine-211 was developed for cancer therapy. The MURR boasts the highest flux university research reactor in the U.S., 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 wide 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 research project to repurpose unwanted waste into valuable assets for U.S. research and approaches completion. The UWM cyclotron distributes a variety of isotopes as well as providing target fabrication services for the UIN. The research staff at both national labs and universities support the development of new production and chemical separations for rare isotopes or isotopes in short supply, specific to the facility at their site, and collaborate to tackle mutual challenges and focus on urgently needed isotopes.

Competitive research funds to universities and national laboratories support targeted high priority 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 in the U.S. in 1981; the U.S. now depends on foreign supplies. Deuterium is disassociated from heavy water and is used in deuterated drugs products, biomedical research, fusion energy research, and semi-conductor manufacturing. Foreign supply has been 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 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.

A high priority of both core and competitive research is the development of transformative medical isotopes to diagnose disease and reduce cancer mortality. Globally, there is escalating interest in alpha and beta emitters for revolutionary cancer and infectious disease therapy and diagnostics. The DOE IP has established itself as the world leader in this arena, typically being 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 ramping up production capabilities of alpha-emitters, including actinium-225 (Ac-225), a high-priority isotope that has shown stunning success in the treatment of diffuse cancers and infections. 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, to bridge the “valley of death” that lies at the intersection of these two federal programs.

The DOE Isotope Initiative, proposed in the FY 2024 Budget, enables a proactive and robust targeted research effort aimed at establishing a domestic supply chain for high-priority, high-impact isotopes, whose progress has been funding-limited; the targeted isotopes are required for the success of federal missions and Administration priorities. As part of the SC BRaVE Initiative, national preparedness is enhanced with equipment and research to produce medical isotopes at the Radioisotope Science Center (RSC) at MURR, mitigating single point failures in the Program and increasing performance and response times during times of national crisis. The RSC is planned to be located in the Discovery Ridge Research Park near the University of Missouri, providing the surrounding underserved rural area with job opportunities in isotope science. Support through the SC Advanced Manufacturing initiative focuses on revolutionary and innovative approaches to isotope production with broader applications in commercial isotope production. 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. As part of the Accelerate initiative, the DOE IP supports research of multi-scale/multi-physics simulations of targets to improve isotope production efficiencies, research to advance the production of industrially relevant quantities of isotopes for a clean energy economy, and approaches that combine advanced manufacturing, AI/ML and novel chemical processes.

Training and development opportunities for students and post-docs are a priority for DOE IP to promote a vibrant, diverse, and inclusive workforce essential for isotope production. DOE IP participates in the RENEW initiative to expand targeted efforts, including a RENEW graduate fellowship, to broaden participation and advance justice, equity, diversity, and inclusion in SC-sponsored research. Participation in the SC FAIR initiative provides opportunities for research, bolstered with investments in equipment and infrastructure at minority serving institutions, including attention to underserved and environmental justice regions. 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; equipment and infrastructure 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 is the steward of several facilities for isotope production and chemical processing and leverages facilities and capabilities across the U.S. government that are owned by other Federal entities for cost effective operations. The DOE IP stewards the Isotope Production Facility (IPF) at LANL and the Brookhaven Linac Isotope Producer (BLIP) facility at BNL; both are proton accelerators that provide year-round continuous availability of critical 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 infrastructure is supported at these sites. In addition, processing capabilities are supported at PNNL for targeted isotopes such as strontium-90 for batteries, 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 for industry and research, and americium-241 for nuclear sources and batteries is recovered from NNSA plutonium processes at the LANL Plutonium Facility. Helium-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 220 stable isotopes from inventory, produces a few stable isotopes, and produces over 81 radioisotopes in short supply for the Nation. The Program is often the only source of these isotopes globally. 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
- lithium-6 neutron detectors for homeland security applications
- 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

The prototype capabilities of the Enriched Stable Isotope Prototype Plant (ESIPP), developed through DOE IP-supported research, demonstrated the feasibility of new EMIS and gas centrifuge (GC) technologies and re-established a small 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 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 disease such as COVID-19.

The SIPRC line-item construction project further expands gas centrifuge isotope separation and EMIS production capability to meet the Nation's growing demand for stable isotopes. CD-1, Approve Alternative Selection and Cost Range, and Subproject-1 CD-3A, Approve Long Lead Procurement, was received on November 4, 2021. 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. Across the Nation, rising construction costs and supply chain issues are impacting project costs, and SIPRC is no exception; these impacts will be assessed at an evidence-based peer review planned in 4Q FY 2023. SIPRC is required to mitigate U.S. dependence for enriched stable isotopes on sensitive countries.

The RPF at ORNL is required to expand chemical processing capacity in the U.S. to mitigate dependence for radioisotopes on sensitive countries. Currently, the lack of radioisotope processing capacity is inhibiting the DOE IP from meeting U.S. demand for critical isotopes and establishing domestic supply chains. The RPF is planned as a Hazard Category 2 nuclear facility, able to process the higher specific activity targets that are irradiated in a reactor, such as HFIR. CD-0, Approve Mission Need, was received on April 29, 2021. The current Total Project Cost (TPC) point estimate is \$425,000,000 with a CD-0 approved TPC range of \$310,000,000 to \$615,000,000.

The CARP facility provides chemical processing infrastructure at BNL for the processing of accelerator-irradiated targets. CARP repurposes an existing nuclear Hazard Category 3 Building and outfits it cost-effectively with hot-cells and infrastructure. Not only will CARP allow the domestic establishment of new accelerator-produced isotopes currently only produced outside of the United States, but it will enable an increase in the availability of highly sought-after alpha-emitting isotopes to decrease cancer mortality. CD-0, Approve Mission Need, was received on December 5, 2022. The CD-0 TPC range is \$60,000,000 to \$80,000,000.

Isotope R&D and Production

Activities and Explanation of Changes

(dollars in thousands)

FY 2023 Enacted	FY 2024 Request	Explanation of Changes FY 2024 Request vs FY 2023 Enacted
Isotope R&D and Production	\$109,451	\$173,051
Isotopes, Research	\$38,827	+\$63,600
<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.</p>	<p>Core research supports the highest impact R&D activities at universities and national laboratories. Advanced, innovative, and novel isotope production and processing technologies will increase the availability of the highest priority isotopes in short supply to promote U.S. independence in isotope supply chains. Competitive research supports the most compelling research to address urgent needs in the development of isotope production or processing techniques. Funding increases for the University Isotope Network, adding niche capabilities. Activities continue implementing the Isotope Harvesting at FRIB, which is nearing completion. Advances in other stable isotope enrichments technologies will be explored. Funding supports research translation research to advance novel medical isotopes to clinical trials. Efforts to promote isotopes for clean energy applications is held flat. Efforts continue to develop isotope production for QIS, as does participation in the SC Advanced Manufacturing, FAIR, and Accelerate initiatives. Participation in RENEW and BRaVE initiatives increases. Funding supports new investments in the microelectronics and DOE Isotope initiatives. Increased research funding enables direct 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 medical isotopes, is provided.</p>	<p>Evidence-based research activities will improve or develop innovative isotope production, enrichment, and processing technology with the goal of increasing domestic supplies of critical isotopes for medicine, energy, national security, and other fields. The increase initiates the DOE Isotope Initiative. The increase will support modest funding to support conceptual design of the CARP at BNL, increased support for the University Isotope Network, and increases to the RENEW and BRaVE initiatives. Funding supports new participation in the microelectronics initiative. Increased funding enables direct support of the Nuclear Chemistry Summer School and participation in the SC Early Career Awards Program. Funding provides OPC funding for CARP to start conceptual design activities.</p>

(dollars in thousands)

FY 2023 Enacted	FY 2024 Request	Explanation of Changes FY 2024 Request vs FY 2023 Enacted
<p>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 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.</p> <p>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>		

(dollars in thousands)

FY 2023 Enacted	FY 2024 Request	Explanation of Changes FY 2024 Request vs FY 2023 Enacted	
Isotopes, Operations	\$46,624	\$78,824	+\$32,200
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 targets.	The Request will support increased mission readiness at all production and processing sites to ~92 percent enabling the Program to better respond as a DOE Mission Essential Function, fill gaps in isotope supply chains and develop new domestic sources of critical isotopes. The Request will provide increased support to NIDC, the business arm of the DOE IP. Funding will continue to support EMIS and development of other enrichment core competencies. Isotopes extracted from legacy reactor target processing, including krypton-85 for semiconductor manufacturing and curium-246/248 to produce Cf-252, will continue. Inventories of isotopes are managed, including He-3 and the stable isotope inventory. Investments target single point failures at the production sites as well as deferred maintenance to ensure safe and reliable operations.	Mission readiness of radioisotope production sites increases to 92 percent. Evidence-based activities will support increased readiness to produce stable isotopes and build up a core competence in stable isotope operations; additional staff commission and operate new enrichment machines. NIDC will add staff to respond to growing inquiries. HFIR remains a workhorse in developing new supply chains for Russian-sourced isotopes, and additional staff continue these efforts. Increased support for the LEAF accelerator at ANL will allow its transition from NNSA to DOE IP. 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, as the first shipments from SRNL reach ORNL for testing. Increased readiness enables the first-time provision of mission readiness support to INL, PNNL, Y-12 and the LANL Plutonium Facility for their efforts in isotope production. Increased funding addresses the highest priority efforts in a backlog of deferred maintenance and performance improvements to increase robust and efficient operations.	
Construction	\$24,000	\$30,400	+\$6,400
U.S. Stable Isotope Production and Research Center (SIPRC)	\$24,000	\$20,900	-\$3,100
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, to provide large scale stable isotope production capacity for the Nation and mitigate U.S. dependence on Russia and Chinese capabilities.	Activities focus on design of gas centrifuges, site preparations, facility construction and EMIS fabrication.	

(dollars in thousands)

FY 2023 Enacted	FY 2024 Request	Explanation of Changes FY 2024 Request vs FY 2023 Enacted	
Radioisotope Processing Facility (RPF)	\$ —	\$8,500	+\$8,500
No funding requested.	The Request will initiate 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 is currently inhibiting production of critical isotopes. RPF is required to mitigate U.S. independence on foreign radioisotope supply chains.	TEC will be initiated for RPF, including engineering design and long lead procurements. RPF proposes to be constructed at ORNL as a greenfield site.	
Clinical Alpha Radionuclide Producer (CARP)	\$ —	\$1,000	+\$1,000
No funding requested.	The Request will initiate TEC of the CARP at BNL. CARP enables the domestic establishment of new accelerator-produced isotopes currently only produced outside of the United States and allows an increase in the availability of highly sought after alpha-emitting isotopes to decrease cancer mortality and meet U.S. demand.	TEC will be initiated for CARP, including engineering design and long lead procurements. CARP repurposes an existing facility at BNL and adds chemical processing infrastructure.	

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

(dollars in thousands)

	Total	Prior Years	FY 2022 Enacted	FY 2023 Enacted	FY 2024 Request	FY 2024 Request vs FY 2023 Enacted
Capital Operating Expenses						
Capital Equipment	N/A	N/A	–	2,000	9,100	+7,100
Total, Capital Operating Expenses	N/A	N/A	–	2,000	9,100	+7,100

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

(dollars in thousands)

	Total	Prior Years	FY 2022 Enacted	FY 2022 IRA Supp.	FY 2023 Enacted	FY 2024 Request	FY 2024 Request vs FY 2023 Enacted
24-SC-91, Radioisotope Processing Facility (RPF), ORNL							
Total Estimated Cost (TEC)	585,000	–	–	–	–	8,500	+8,500
Other Project Cost (OPC)	29,406	–	3,000	10,600	1,000	–	-1,000
Total Project Cost (TPC)	614,406	–	3,000	10,600	1,000	8,500	+7,500
24-SC-92, Clinical Alpha Radionuclide Producer (CARP), BNL							
Total Estimated Cost (TEC)	70,000	–	–	–	–	1,000	+1,000
Other Project Cost (OPC)	10,000	–	–	–	–	1,500	+1,500
Total Project Cost (TPC)	80,000	–	–	–	–	2,500	+2,500
20-SC-51, SIPRC							
Total Estimated Cost (TEC)	288,800	–	12,000	75,000	24,000	20,900	-3,100
Other Project Cost (OPC)	6,600	–	3,200	–	–	–	–
Total Project Cost (TPC)	295,400	–	15,200	75,000	24,000	20,900	-3,100
Total, Construction							
Total Estimated Cost (TEC)	N/A	N/A	12,000	75,000	24,000	30,400	+6,400
Other Project Cost (OPC)	N/A	N/A	6,200	10,600	1,000	1,500	+500
Total Project Cost (TPC)	N/A	N/A	18,200	85,600	25,000	31,900	+6,900

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-O 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 2022 Enacted	FY 2023 Enacted	FY 2024 Request	FY 2024 Request vs FY 2023 Enacted
Number of Permanent Ph.Ds (FTEs)	33	41	57	+16
Number of Postdoctoral Associates (FTEs)	19	30	34	+4
Number of Graduate Students (FTEs)	17	33	45	+12
Number of Other Scientific Employment (FTEs)	89	103	140	+37
Total Scientific Employment (FTEs)	158	207	276	+69

Note:

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

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

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

Summary

The FY 2024 Request for the Radioisotope Processing Facility (RPF) is \$8,500,000 of Total Estimated Cost (TEC) funding. The current Total Project Cost (TPC) point estimate is \$425,000,000 with a CD-0 approved TPC range of \$310,000,000 to \$615,000,000.

Significant Changes

This project data sheet (PDS) is a new start in FY 2024. 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 funds activities which finalize the conceptual design of the facility, modular hot cell units, and radiochemical equipment in preparation for CD-1/3A. The IRA support avoids projected reductions-in-force, reduces project risks, and enables early value engineering. TEC funding in FY 2024 will support engineering design activities and initiate long-lead procurements for the design-build modular hot cell units; funding will also support early site preparation activities such as geotechnical sampling, tree clearing, and cut and fill operations to prepare the site.

A Federal Project Director (FPD) is in the process of being assigned to the ORNL RPF and will be in place by CD-1.

Critical Milestone History

Fiscal Year	CD-0	Conceptual Design Complete	CD-1	CD-2	Final Design Complete	CD-3	CD-4
FY 2024	4/29/21	2Q FY 2024	3Q FY 2024	1Q FY 2027	TBD	1Q FY 2027	4Q FY 2033

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
FY 2024	1Q FY 2027	3Q FY 2024

Project Cost History

This project has a pre-CD-1 preliminary point estimate of \$425,000,000 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 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	48,500	536,500	585,000	30,000	30,000	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 45,000 square feet, and the associated equipment for production of priority 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 should 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 high-priority commodities essential for energy, medical, space, environmental, and national security applications and for basic research. Currently, radioisotope processing facility capacity, including required elements 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. There is a shortage of radioisotope processing capabilities to process irradiated reactor targets, such as from the High Flux Isotope Reactor (HFIR) at Oak Ridge National Lab, a pivotal facility in the DOE IP which produces a suite of high priority radioisotopes for the Nation. The facility will enable radioisotope processing infrastructure to meet the near-and long-term needs of the DOE IP, 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	IRA Supp. Costs
Total Estimated Cost (TEC)				
Design (TEC)				
FY 2024	8,500	8,500	8,500	—
Outyears	40,000	40,000	40,000	—
Total, Design (TEC)	48,500	48,500	48,500	—
Construction (TEC)				
Outyears	536,500	536,500	536,500	—
Total, Construction (TEC)	536,500	536,500	536,500	—
Total Estimated Cost (TEC)				
FY 2024	8,500	8,500	8,500	—
Outyears	576,500	576,500	576,500	—
Total, TEC	585,000	585,000	585,000	—

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Other Project Cost (OPC)				
Prior Years	594	594	—	—
FY 2022	3,000	3,000	3,594	—
FY 2022 - IRA Supp.	10,600	10,600	—	—
FY 2023	1,000	1,000	1,000	10,600
Outyears	14,806	14,806	14,806	—
Total, OPC	30,000	30,000	19,400	10,600

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Total Project Cost (TPC)				
Prior Years	594	594	–	–
FY 2022	3,000	3,000	3,594	–
FY 2022 - IRA Supp.	10,600	10,600	–	–
FY 2023	1,000	1,000	1,000	10,600
FY 2024	8,500	8,500	8,500	–
Outyears	591,306	591,306	591,306	–
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	35,000	N/A	N/A
Design - Contingency	13,500	N/A	N/A
Total, Design (TEC)	48,500	N/A	N/A
Construction	360,000	N/A	N/A
Construction - Contingency	176,500	N/A	N/A
Total, Construction (TEC)	536,500	N/A	N/A
Total, TEC	585,000	N/A	N/A
Contingency, TEC	190,000	N/A	N/A
Other Project Cost (OPC)			
Conceptual Design	12,194	N/A	N/A
Start-up	9,306	N/A	N/A
OPC - Contingency	8,500	N/A	N/A
Total, Except D&D (OPC)	30,000	N/A	N/A
Total, OPC	30,000	N/A	N/A
Contingency, OPC	8,500	N/A	N/A
Total, TPC	615,000	N/A	N/A
Total, Contingency (TEC+OPC)	198,500	N/A	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 2022	FY 2022 IRA Supp.	FY 2023	FY 2024	Outyears	Total
FY 2024	TEC	—	—	—	—	8,500	576,500	585,000
	OPC	594	3,000	10,600	1,000	—	14,806	30,000
	TPC	594	3,000	10,600	1,000	8,500	591,306	615,000

6. Related Operations and Maintenance Funding Requirements

Start of Operation or Beneficial Occupancy	4Q FY 2033
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	—	N/A	—
Utilities	N/A	—	N/A	—
Maintenance and Repair	N/A	—	N/A	—
Total, Operations and Maintenance	N/A	—	N/A	—

7. D&D Information

	Square Feet
New area being constructed by this project at ORNL.....	~45,000
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 2024 Request for the 24-SC-92, Clinical Alpha Radionuclide Producer (CARP) facility is \$2,500,000, including \$1,000,000 of Total Estimated Cost (TEC) funding and \$1,500,000 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 a new start in FY 2024. 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 2024, 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 2024, TEC funding will initiate preliminary design activities.

A Federal Project Director (FPD) has not yet been assigned to the BNL CARP, but one will be assigned by CD-1.

Critical Milestone History

Fiscal Year	CD-0	Conceptual Design Complete	CD-1	CD-2	Final Design Complete	CD-3	CD-4
FY 2024	12/5/22	TBD	4Q FY 2024	4Q FY 2025	TBD	4Q FY 2025	4Q FY 2029

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
FY 2024	4Q FY 2025	4Q FY 2024

Project Cost History

The table below reflects the upper cost of the TPC range as there is not yet a baseline. 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	6,500	63,500	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 6,000 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 the irradiated thorium 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 by design”, “quality by design”, and “safeguards by design” standards to ensure safe and efficient future operations.

Justification

CARP is critical to the Nation and to the DOE Isotope Program (DOE IP) within SC’s Office of Isotope R&D and Production. Radioisotope processing needs to be performed in facilities that carry a Hazard Category designation. The nuclear facility hazard category (i.e., Hazard Category 1, 2, 3, or below 3—“radiological facility”) defines the maximum quantity and type of radioactive material that can be present within a facility. This facility will enable DOE IP to better meet U.S. demand for isotopes and mitigate supply chain interruptions for critical radioisotopes. Without this facility, DOE IP will limit radioisotope processing operations to the sub-Hazard Category 3 level, resulting in significant constraints on the amount of material that can be processed, smaller batch sizes, and fewer concurrent processing activities. Isotope production and processing at one of the DOE IP radioisotope production flagship facilities, the Brookhaven Linac Isotope Producer (BLIP), will be significantly impacted. The CARP facility will enable DOE IP to continue its mission of isotope production at BLIP as a DOE Mission Essential Function 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 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	1,000	1,000	1,000
Outyears	5,500	5,500	5,500
Total, Design (TEC)	6,500	6,500	6,500
Construction (TEC)			
Outyears	63,500	63,500	63,500
Total, Construction (TEC)	63,500	63,500	63,500
Total Estimated Cost (TEC)			
FY 2024	1,000	1,000	1,000
Outyears	69,000	69,000	69,000
Total, TEC	70,000	70,000	70,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Other Project Cost (OPC)			
FY 2024	1,500	1,500	1,500
Outyears	8,500	8,500	8,500
Total, OPC	10,000	10,000	10,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Total Project Cost (TPC)			
FY 2024	2,500	2,500	2,500
Outyears	77,500	77,500	77,500
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	4,500	N/A	N/A
Design - Contingency	2,000	N/A	N/A
Total, Design (TEC)	6,500	N/A	N/A
Construction	42,500	N/A	N/A
Construction - Contingency	21,000	N/A	N/A
Total, Construction (TEC)	63,500	N/A	N/A
Total, TEC	70,000	N/A	N/A
<i>Contingency, TEC</i>	<i>23,000</i>	<i>N/A</i>	<i>N/A</i>
Other Project Cost (OPC)			
Conceptual Design	4,000	N/A	N/A
Start-up	3,000	N/A	N/A
OPC - Contingency	3,000	N/A	N/A
Total, Except D&D (OPC)	10,000	N/A	N/A
Total, OPC	10,000	N/A	N/A
<i>Contingency, OPC</i>	<i>3,000</i>	<i>N/A</i>	<i>N/A</i>
Total, TPC	80,000	N/A	N/A
Total, Contingency (TEC+OPC)	26,000	N/A	N/A

5. Schedule of Appropriations Requests

(dollars in thousands)

Fiscal Year	Type	Prior Years	FY 2022	FY 2023	FY 2024	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

6. Related Operations and Maintenance Funding Requirements

Start of Operation or Beneficial Occupancy	4Q FY 2029
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

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 2024 Request for the U.S. Stable Isotope Production and Research Center (SIPRC) is \$20,900,000 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 2023 PDS; the project is not a new start in FY 2024. The most recent DOE Order 413.3B approved Critical Decision (CD) is CD-1, Approve Alternative Selection and Cost Range and Subproject 1 CD-3A, Approve Long-Lead Procurement, which was approved on November 4, 2021; the project is not baselined. The TPC point estimate increased from \$250,000,000 to \$325,000,000, remaining within the CD-1 approved TPC range of \$187,000,000 to \$338,000,000. The increase is primarily driven by COVID-19 supply chain impacts which have created an environment of long-lived increasing costs especially for facility construction and materials. The point estimate also reflects the result of advancing project maturity with the progression of the preliminary engineering design. The increase and the TPC point estimate will be thoroughly assessed through an evidence-based peer-review in late FY 2023. The current TPC point estimate is anticipated to remain within the TPC range established at CD-1. In early FY 2023, driven by an extraordinary increase in lead times for critical EMIS magnet components, the project pursued Subproject 1 CD-3B, Approve Long-Lead Procurement, as a risk mitigation strategy. Approval of CD-3B is anticipated for mid-FY 2023.

The project received Inflation Reduction Act (IRA) funding in FY 2022, supporting the SIPRC facility construction award contract planned for early FY 2024 and maintains optimal project progress throughout that year; IRA funding also pulls forward the CD-4 from FY 2032 to FY 2031. The FY 2024 Request will continue support for Project Engineering and Design (PED) activities and approved long-lead procurements, which are based on known designs of technologies developed under previous efforts. Due to an anticipated CD-2/3, Approve Performance Baseline and Approve Start of Construction, approval of SIPRC Subproject 1 (SP-1) in early FY 2024. The FY 2024 Request will also support activities such as the facility construction and EMIS machine component procurements.

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 2025	4Q FY 2025	4Q FY 2025	4Q FY2031
SIPRC SP-1 - Facility and EMIS	1/4/19	2/26/21	11/4/21	1Q FY 2024	1Q FY 2024	1Q FY 2024	1Q FY 2030
SIPRC SP-2 - Mo-100 Cascade	1/4/19	2/26/21	11/4/21	4Q FY 2025	4Q FY 2025	4Q FY 2025	4Q FY 2031
SIPRC SP-3 - Si-28 Test Cascade Infrastructure	1/4/19	2/26/21	11/4/21	4Q FY 2025	4Q FY 2025	4Q FY 2025	4Q FY 2031

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 2025	4Q FY 2025	2Q FY 2023
SIPRC SP-1 - Facility and EMIS	1Q FY 2024	11/4/21	2Q FY 2023
SIPRC SP-2 - Mo-100 Cascade	4Q FY 2025	4Q FY 2025	–
SIPRC SP-3 - Si-28 Test Cascade Infrastructure	4Q FY 2025	4Q FY 2025	–

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-3B 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).

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 2023	36,000	201,800	237,800	12,200	12,200	250,000
FY 2024	36,000	276,800	312,800	12,200	12,200	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 critical 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 nurtures 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 the operability demonstration by running simultaneously with gas for 4 hours.	SP-1 – Facility and EMIS: One hundred percent (100 percent) of the EMIS machines complete the operability demonstration by running simultaneously 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.
	SP-3 – Si-28 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 – Si-28 Test Cascade Infrastructure: The SIPRC project will successfully complete an operability test of the TCI's feed and withdrawal system using a defined gas, either surrogate or actual planned SiF4 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	12,000	12,000	–	–
FY 2022	9,000	9,000	11,500	–
FY 2023	6,000	6,000	11,500	–
FY 2024	6,000	6,000	9,500	–
Outyears	3,000	3,000	3,500	–
Total, Design (TEC)	36,000	36,000	36,000	–
Construction (TEC)				
Prior Years	12,000	12,000	–	–
FY 2022	3,000	3,000	13,800	–
FY 2022 - IRA Supp.	75,000	75,000	–	–
FY 2023	18,000	18,000	–	35,000
FY 2024	14,900	14,900	30,000	40,000
Outyears	153,900	153,900	158,000	–
Total, Construction (TEC)	276,800	276,800	201,800	75,000
Total Estimated Cost (TEC)				
Prior Years	24,000	24,000	–	–
FY 2022	12,000	12,000	25,300	–
FY 2022 - IRA Supp.	75,000	75,000	–	–
FY 2023	24,000	24,000	11,500	35,000
FY 2024	20,900	20,900	39,500	40,000
Outyears	156,900	156,900	161,500	–
Total, TEC	312,800	312,800	237,800	75,000

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Other Project Cost (OPC)				
Prior Years	5,600	5,600	5,600	–
FY 2022	3,200	3,200	3,200	–
Outyears	3,400	3,400	3,400	–
Total, OPC	12,200	12,200	12,200	–

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs	IRA Supp. Costs
Total Project Cost (TPC)				
Prior Years	29,600	29,600	5,600	—
FY 2022	15,200	15,200	28,500	—
FY 2022 - IRA Supp.	75,000	75,000	—	—
FY 2023	24,000	24,000	11,500	35,000
FY 2024	20,900	20,900	39,500	40,000
Outyears	160,300	160,300	164,900	—
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	30,000	27,000	N/A
Design - Contingency	6,000	9,000	N/A
Total, Design (TEC)	36,000	36,000	N/A
Construction	200,000	150,000	N/A
Construction - Contingency	76,800	51,800	N/A
Total, Construction (TEC)	276,800	201,800	N/A
Total, TEC	312,800	237,800	N/A
<i>Contingency, TEC</i>	<i>82,800</i>	<i>60,800</i>	<i>N/A</i>
Other Project Cost (OPC)			
R&D	N/A	2,600	N/A
Conceptual Design	8,000	4,100	N/A
Start-up	2,500	2,100	N/A
OPC - Contingency	1,700	3,400	N/A
Total, Except D&D (OPC)	12,200	12,200	N/A
Total, OPC	12,200	12,200	N/A
<i>Contingency, OPC</i>	<i>1,700</i>	<i>3,400</i>	<i>N/A</i>
Total, TPC	325,000	250,000	N/A
Total, Contingency (TEC+OPC)	84,500	64,200	N/A

5. Schedule of Appropriations Requests^a

(dollars in thousands)

Fiscal Year	Type	Prior Years	FY 2022	FY 2022 IRA Supp.	FY 2023	FY 2024	Outyears	Total
FY 2023	TEC	24,000	12,000	—	12,000	—	189,800	237,800
	OPC	5,600	3,200	—	—	—	3,400	12,200
	TPC	29,600	15,200	—	12,000	—	193,200	250,000
FY 2024	TEC	24,000	12,000	75,000	24,000	20,900	156,900	312,800
	OPC	5,600	3,200	—	—	—	3,400	12,200
	TPC	29,600	15,200	75,000	24,000	20,900	160,300	325,000

6. Related Operations and Maintenance Funding Requirements

Start of Operation or Beneficial Occupancy	1Q FY 2030
Expected Useful Life	30 years
Expected Future Start of D&D of this capital asset	1Q FY 2060

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

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.

^a The project does not have CD-2 approval; FY 2024 schedules and costs are estimates consistent with the updated preliminary point estimate.

Isotope Production and Distribution Program Fund

Overview

The Department of Energy's (DOE) Isotope Production and Distribution Program Fund, more commonly called the DOE Isotope Program (DOE IP), provides critical isotopes in short supply to the Nation 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. Isotopes are foundational to essential applications that benefit society every day, such as revolutionary cancer therapy, diagnostic medical imaging, clean energy, explosives detection, quantum computing, advanced manufacturing, nuclear batteries, space exploration, national security, and biological tracers. In some cases, the DOE IP is the Nation's sole supplier of radioisotopes used in human clinical trials and/or in FDA-approved radiopharmaceuticals. A priority of the DOE IP is to mitigate the Nation's dependency on foreign supply chains of isotopes, particularly those from sensitive countries.

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 (from the Office of Isotope R&D and Production Program [IRP or DOE IP]) and collections from isotope sales; both are needed to maintain the Isotope Program's viability. Isotopes sold to commercial customers are priced to recover the full cost of production or the market price (whichever is higher). Research isotopes are sold at a reduced price to ensure that the high priority research requiring them does not become cost prohibitive. The 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 as a DOE Mission Essential Function during times of national crisis. During COVID-19 and the Russian invasion of Ukraine, the program has mitigated disruptions in isotope supply chains. An independent cost review of the fund's revenues and expenses is conducted annually by an external contractor.

The DOE IP produces radioisotopes by irradiating targets in accelerators or reactors at national laboratories and universities, and from extraction of materials from legacy waste, and strategic inventories. Accelerator facilities include the Brookhaven Linac Isotope Producer at Brookhaven National Laboratory, the Isotope Production Facility at Los Alamos National Laboratory, the Low Energy Accelerator Facility at Argonne National Laboratory, the University of Washington cyclotron, the University of Alabama-Birmingham cyclotron, and the University of Wisconsin-Madison cyclotron. Reactor facilities include the High Flux Isotope Reactor at Oak Ridge National Laboratory (ORNL), the University of Missouri Research Reactor, and the Advanced Test Reactor at Idaho National Laboratory. Irradiated targets are processed in associated hot cells and gloveboxes at these facilities. Isotopes are also extracted and purified at the Y-12 National Security Complex, the Pacific Northwest National Laboratory, and the Savannah River Site. Enriched stable isotopes are distributed from inventory and produced in modest amounts at ORNL with modern electromagnetic ion separating devices. The DOE IP can produce over 81 radioisotopes in short supply and distribute over 220 stables to the Nation. More details on these isotopes can be found in the DOE IP budget request in the Office of Science.

The National Isotope Development Center (NIDC) is the business arm of the DOE IP and manages contractual obligations with customers, marketing, and isotope production coordination. Given the myriad of supply chain disruptions from the Russian invasion of Ukraine, an immense amount of time was spent with stakeholders in FY 2022 and FY 2023 to understand the health of supply chains, ease customer concerns, and develop alternate sourcing of supplies. The NIDC organized stakeholder meetings throughout each year, including multiple several day sessions of dedicated meetings with industrial representatives. User group meetings of four promising medical isotopes to combat cancer were organized by the NIDC to promote information exchange between industry and research institutions. A DOE IP booth was presented at two international conferences in FY 2022 to conduct outreach and meet with stakeholders.

Annual appropriations in the DOE IP program support a payment into the revolving fund to maintain mission-readiness of facilities, including the support of core scientists and engineers needed to produce and process isotopes, and the maintenance and enhancement of isotope facilities and capabilities to assure reliable production and provide novel isotopes in high demand and short supply. In addition, appropriated funds provide support for R&D activities associated with development of new production and processing techniques for isotopes and workforce development in isotope production and chemical processing. 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. Revenues are collected from customers to offset the costs of producing, dispensing, packaging, and shipping isotopes; these revenues are also deposited into the revolving fund. About 80 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 20 percent available for process improvements, unanticipated changes in revenue, manufacturing equipment, capability and infrastructure upgrades, and capital equipment such as assay equipment, glove boxes, and shipping containers needed to ensure on-time deliveries.

In FY 2023, a total of \$148.5 million is estimated to be deposited into the revolving fund for isotope sales and technical services. This consists of the FY 2023 appropriation of \$97.5 million paid into the revolving fund from the Isotope R&D and Production program, plus anticipated collections by NIDC of \$51.0 million to recover costs related to isotope production and isotope services. In FY 2023, 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 2024 Request

For FY 2024, 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. With the new DOE Isotope Initiative in FY 2024, the Program is focused on developing U.S. independence from Russian isotope supply chains; the Isotope Initiative will enable 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 FY 2024 Request of the DOE IP Budget is \$173.1 million. 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.
- Operate as a Departmental Mission Essential Function, supporting 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.
- Through cutting-edge research and advanced manufacturing, introduce novel and critical isotopes to the Nation to facilitate emerging technology and applications (medicine, quantum computing, clean energy, nuclear batteries...), promoting U.S. economic prosperity and technical strengths.
- Mitigate U.S. dependence on foreign supply chains and promote domestic production capabilities with technology transfer.
- Advance and expand transformative, domestic stable isotope enrichment capabilities.
- Enhance isotope processing capabilities to address a lack of infrastructure 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 infrastructure needs.

Program Accomplishments

Rare Isotope Made Available to Promote Commercialization and Advance R&D

Radium-226 (Ra-226) was made famous through Marie Curie's research. Decades ago, it was used in various medical treatments, including in small needles, tubes, and plaques. Once those treatments were proven ineffective and some of the hazards of handling radium were better understood, those small needles, tubes, and plaques were collected and stored in

various waste drums throughout the world. In the modern era, scientists have discovered how to use Ra-226 as a source material for producing the new generation of alpha-emitting radioisotopes, including actinium-225 (Ac-225). Over the past decade, DOE has acquired some of this “waste” Ra-226 and subsequently developed the means to recycle and purify it into the needed starting material/feedstock for production of radioisotopes. In FY 2022, DOE announced the availability of R&D quantities of Ra-226 so that other organizations can also develop supply chains for these new alpha-emitters to develop a robust U.S. supply. DOE is currently the only supplier of this limited Ra-226 starting material, other than Russia.

Record Breaking number of Shipments of New Cancer-Fighting Isotope

Transporting radioisotopes is a non-trivial task requiring specialized shipping containers and stringent packaging steps to ensure worker and public safety. These critical steps become all the more challenging when delivering isotopes with a short half-life, such as actinium-225 (Ac-225). Ac-225 is showing tremendous advances in the fight against cancer such as Acute Myeloid Leukemia, Colorectal Cancer, Prostate Cancer, Multiple Myeloma, and others. But with a drug shelf-life of some 3-days and the underlying Ac-225 half-life of ~10-days, reliable and safe weekly shipments of Ac-225 are required for patient care. The DOE IP is the world leader in the production of Ac-225, followed by Russia and Germany. In FY 2022, the DOE achieved record levels of distribution by making over 500 shipments totaling over 1 million micro-curies of Ac-225 to support patient treatments and clinical trials.

U.S. Production Demonstration of Ytterbium Isotopes Using Newly Developed Stable Isotope Enrichment Equipment Leads to Cutting-edge Cancer Therapies and Quantum Science Applications

ORNL is routinely enriching the stable isotopes of ytterbium using the latest generation of electromagnetic isotope separation (EMIS) technology developed and deployed at ORNL. Ytterbium-176 (Yb-176) has been enriched at or above the isotopic purity required for production of the radioisotope lutetium-177, which is the active ingredient in an FDA-approved radiopharmaceutical used to treat pancreatic cancer. The DOE IP entered the market for Yb-176 sales in FY 2022. Prior to the success of the ORNL EMIS technology, Russia was the sole supplier of Yb-176 and was limiting U.S. availability. Other isotopes of ytterbium are simultaneously enriched with the same EMIS device, including Yb-171 and Yb-172, which have application in quantum information science.