Isotope R&D and Production

Overview

The DOE Isotope Program (DOE IP), which includes both the appropriated funding requested in the Isotope R&D and Production (IRP) program, as well as collections in the revolving fund, produces critical radioactive and stable isotopes in short supply for the Nation that no domestic entity has the infrastructure or core competency to produce; the Program is typically the only, or one of few, global or domestic producers for these novel isotopes. Isotopes are high-priority commodities of strategic importance for the Nation and are essential in medical diagnosis and treatment, discovery science, national security and preparedness, industrial processes and advanced manufacturing, space exploration and communications, biology, archaeology, quantum science, clean energy, environmental science, and other fields. Isotopes can directly enable emerging technology, and contribute to the economic, technical and scientific strength of the United States. The mission of the DOE IP is to:

- Produce and/or distribute radioactive and enriched stable isotopes that are in short supply or not produced in the U.S., including valuable by-products and related isotope services.
- Ensure National preparedness for critical isotope production and distribution by maintaining mission readiness of relevant national infrastructure and core competencies, to ensure functionality even during times of national crisis.
- Conduct advanced R&D to develop innovative technology, advanced radiochemical separations and purifications, and unique and diverse core competencies to create or improve entirely novel isotope production and radiochemistry processing capability.
- Mitigate U.S. dependence on foreign supplies of isotopes and ensure robust domestic supply chains.

The DOE IP utilizes particle accelerators, nuclear research reactors, enrichment technologies, and radiochemical processing capabilities throughout the national laboratory complex and at universities that it stewards, or leverages capabilities stewarded by other federal programs or academic institutions to most cost effectively utilize national capabilities to meet the requirements of the Nation in isotope demand. During the COVID-19 pandemic, the DOE IP continued operating as a department “Mission Essential Function” to ensure stability in critical supply chains and intervened multiple times to fill gaps in international disruptions in supply chains of critical isotopes for medical applications. The DOE IP works closely with U.S. industry to ensure availability of adequate, high quality isotopic supply for continued stability and planned growth, and facilitates commercialization of isotope production to the domestic private sector. The DOE IP supports world-leading research and development associated with creating innovative and more efficient isotope production and processing techniques. The R&D activities provide collateral benefits for training, workforce development, and promotion of a future U.S.-based expertise relevant to nuclear energy, accelerator science, nuclear engineering, nuclear physics, isotope enrichment, and nuclear chemistry and radiochemistry. These disciplines are foundational, not only to isotope production and processing, but underpin many critical aspects of basic and applied nuclear and radiochemical science.

The DOE IP manages federal inventories of key isotopes, such as helium-3 for cryogenics and other applications, and the national repository for all stable isotopes that were created by calutrons (electro-magnetic ion separation) developed as part of the Manhattan Project; the calutrons ceased operations in 1998. The U.S. inventory of stable isotopes is limited or has even been depleted in some cases, causing the U.S. to be dependent on foreign supply chains for certain stable isotopes. The DOE IP has developed and implemented modern stable isotope enrichment capabilities to replenish supplies and promote U.S. independence from foreign supply. The DOE IP also considers DOE-owned legacy waste or inventories and extracts isotopes of interest to re-purpose unwanted or excess materials and reduce waste disposal.

The National Isotope Development Center (NIDC) is located at the Oak Ridge National Laboratory (ORNL) and is responsible for the day-to-day business operations of the programs, including sales, contract negotiation, marketing assessment, public outreach, quality control, packaging and transportation. The NIDC interfaces regularly with industry, research, and medical communities to gauge future needs since new isotopes can take years of research and development to bring to market.

All funding for DOE IP is executed through the Isotope Production and Distribution Program revolving fund. The isotope revolving fund maintains its financial viability by utilizing this appropriation for the Isotope R&D and Production Office, along with collections from customers for the sale of isotopes and services. The funds in this Budget Request are used to ensure mission readiness of the staff, facilities, and capabilities; to support R&D activities related to the production and processing of isotopes; and to strengthen and develop new capabilities to meet the growing demand of the Nation for isotopes. The customer collections pay for the activities associated with the actual production, distribution, and related services of the isotope. Isotopes sold to commercial customers are priced to recover the full cost of production, or if a market actually exists, 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.

Highlights of the FY 2022 Request

In FY 2022, the DOE IP anticipates continued growth in novel isotope demand, especially for medicine, nuclear batteries, space applications, clean energy, national security, biology, discovery research and quantum computing. In medicine, there is 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 of interest or leading the way in transformative research to make them available. Interests in isotopes for biological imaging and as biological tracers continue to rise. There is a current global shortage for isotopes needed for nuclear batteries and the DOE IP is positioning itself to enter a market in which there is only one other foreign producer. Interests in isotopes for space applications are also on the rise, and the DOE IP anticipates working with an increasing number of industrial entities in testing isotopes for nuclear batteries used in space applications and producing novel isotopes for atomic clocks used in satellite communications.

In FY 2022, mission readiness of both radio- and stable isotope production facilities modestly increases over levels in the FY 2021 Enacted Appropriation. The DOE IP is not able to keep pace with incoming requests for stable isotopes and is developing additional stable isotope enrichment capabilities as quickly as it can. The only other global producers/exporters of enriched stable isotopes are Russia, followed by the Netherlands. The implementation of the Stable Isotope Production Facility (SIPF) Major Item of Equipment (MIE) is continued, and funds in FY 2022 are requested for pre-operations funding to start commissioning SIPF gas centrifuges (GC) to produce enriched Xenon-129. Xenon-129 is the newest isotope to show its effectiveness in polarized lung imaging; there is 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 FY 2022 Request includes $3.2 million in Other Project Cost (OPC) and $12.0 million in Total Estimated Cost (TEC) funding to continue the U.S. Stable Isotope Production and Research Center (SIPRC) at ORNL, which will significantly enhance stable isotope production capacity for the Nation. SIPRC will build upon the expertise in centrifuge and electromagnetic isotope separation (EMIS) technology nurtured by SIPF and the Enriched Stable Isotope Prototype Plant (ESIPP) to enable multiple production campaigns of critical stable isotopes simultaneously.

Funding in research strengthens or initiates participation in several high priority Office of Science initiatives. The DOE IP joins the SC Fundamental Science to Transform Advanced Manufacturing Initiative and pursues transformative approaches to target advanced manufacturing, such as ink jet printing of thin film targets for isotope production, and modular automated systems for radioisotope purification and processing. In cooperation with the NIH, the DOE IP focuses on research facilitating the translation of novel radioisotopes and targeted delivery agents from the laboratory to use in clinical trials for both diagnosis and treatment of disease, supporting a known "valley of death" that lies at the intersection of these two federal programs. As part of the Biopreparedness Research Virtual Environment (BRaVE) Initiative, the DOE IP will tackle what has become a significant obstacle and single point failure in the program, processing of irradiated nuclear reactor targets. This is actively limiting the ability of the Program to make available certain new isotopes and provide assurance of the Nation's readiness to respond to disruptions in global isotope supply chains. Funding will develop short-term reactor target processing capabilities at the University of Missouri Research Reactor (MURR) and further develop the conceptual design of a new long-term facility at ORNL, the ORNL Radioisotope Processing Facility (RPF). Increased investment in the ongoing SC Quantum Information Sciences (QIS) Initiative will advance development of cutting-edge technology for the production of isotopes of interest to QIS. Funding continues the Isotope Program Traineeship to promote innovative and transformative approaches to isotope production and processing, such as advanced manufacturing, artificial intelligence and machine learning, and robotics; the Traineeship emphasizes participation of minority serving institutions and increasing the diversity of the program.

The portfolio of production capabilities in the DOE IP continues to grow to meet the rapidly changing needs of U.S. Federal Agencies, the medical community, industry and academia. The FY 2022 Request continues the Facility for Rare Isotope

Beams (FRIB) Isotope Harvesting at Michigan State University effort, which adds the capabilities to extract and process significant quantities of isotopes from the beam dump of the FRIB, cost effectively repurposing unwanted product. FRIB is a Nuclear Physics DOE Scientific User Facility dedicated to the study of nuclear structure and astrophysics research. Funding supports newcomers to the DOE IP, an inherited radioisotope separation system at Idaho National Laboratory (INL) that can make small quantities of highly enriched and pure isotopes for the nuclear forensics community; and a modest increase for the new group at Argonne National Laboratory (ANL) that brought to the Program an electron accelerator for novel isotope production. The FY 2022 Request also continues increased funding to prepare ORNL facilities for the receipt, storage, and processing of the heavy curium product stream (for use in californium-252 and actinide production) coming from 65 Mark 18-A targets from the National Nuclear Security Administration (NNSA) recovery project at the Savannah River Site (SRS).

<u>Research</u>

The DOE IP supports core research groups at ANL, Brookhaven National Laboratory (BNL), INL, Los Alamos National Laboratory (LANL), ORNL, and Pacific Northwest National Laboratory (PNNL) to conduct transformative research for novel or advanced production and separation techniques for high priority isotopes in short supply. A high priority of the DOE IP remains the dedicated research effort to develop large scale production capabilities of the alpha-emitter actinium-225 (Ac-225), a high priority isotope that has shown stunning success in the treatment of diffuse cancers and infections; in the past, available quantities of Ac-225 derived from thorium-229 (Th-229) have limited clinical trials and applications. The DOE IP leads the world in the provision of Ac-225 and development of novel production routes. DOE IP now routinely produces accelerator-produced Ac-225 and is continuing research to develop efficient full-scale production and processing capabilities to enable sufficient supply of the isotope for cancer treatment.

The lack of processing capabilities for processing irradiated reactor targets is significantly limiting the DOE IP in making available new isotopes and represents a single point failure in national preparedness to respond to disruptions in global isotope supply chains. As part of the SC Biopreparedness Research Virtual Environment (BRaVE) Initiative, research enables a scientific and technical workforce and capability to process reactor targets at MURR in order to introduce domestic supplies of critical isotopes to the Nation, such as iridium-192 for industrial radiography and lutetium-177 for prostate cancer. In parallel, scientists and engineers are developing options and the conceptual design of the Radioisotope Processing Facility for new long-term capabilities at ORNL.

Competitive research funds to universities and national laboratories support activities in a myriad of efforts, including research to alleviate the current U.S. dependence on foreign sources of deuterium, which was last produced in the U.S. in 1981. Deuterium is used in the development, production, and sale of compounds used in chemistry, biomedical and diagnostic research, environmental analysis and physics. Research topics include production of highly enriched lithium-7 for molten salt reactors, new sources of helium-3 for cryogenics, advanced manufacturing approaches to isotope production, critical nuclear data measurements, novel radioisotope enrichment technology, next generation targetry, modular automated systems, the application of machine learning and artificial intelligence to isotope production, and production of neptunium-236 for nuclear forensics. Scientists conduct translational research aimed at facilitating promising isotopes for use in clinical trials for the diagnosis and treatment of infectious disease and cancer; activities focus on basic chemistry (chelates, labeling, stability), biodistribution, toxicity, and dosimetry research that is necessary to develop sufficient data to be able to apply for an NIH grant for drug development.

Scientists perform simulations and conduct cutting-edge research to develop stable isotope enrichment capabilities. Every stable isotope enriched requires an intense and independent research campaign. Current efforts include ytterbium (Yb)-176 as feedstock for isotopes that treat prostate cancer, Yb-171 for quantum memory, xenon (Xe)-129 for polarized lung imaging, and molybdenum (Mo)-100 as feedstock for Mo-99 production. Dedicated machines are designed and optimized for isotopes of interest for quantum computing. In addition, as this technology is dual-use, nurturing a core competency in this technology is vital to the Nation. R&D associated with purification and processing of the existing isotope inventory continues and other enrichment technologies are investigated. 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.

The DOE IP supports universities with unique capabilities, such as the multi-particle cyclotron at the University of Washington where full-scale production of astatine-211 was developed to support research into the use of the isotope in cancer therapy; and the University of Missouri Research Reactor which the DOE IP uses for the production of lutetium (Lu)-177 for cancer therapy research, and selenium-75 for biomedical research. Funding also supports implementation of isotope production capabilities at additional facilities at Texas A&M University, the University of Alabama-Birmingham, University of Pennsylvania, and the University of Wisconsin. The coordinated university network is designed to leverage the unique and often underutilized facilities available at academic institutions which are generally more suited to low-energy production reactions and can support nationwide availability of short-lived radioisotopes.

Emphasis is placed on providing training opportunities to students and post-docs to help assure a vibrant diverse workforce essential to the technologies associated with isotope production. In addition to the recently initiated DOE IP Traineeship Program which supports undergraduate and graduate students, the DOE IP also sponsors workshops at professional society meetings to promote communication of advances in isotope availability 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.

<u>Facility Operations</u>

The DOE IP is the steward of several facilities for isotope production and processing, and in addition, leverages facilities and capabilities across the United States government complex that are owned by other federal entities. The DOE IP stewards the Isotope Production Facility (IPF) at LANL, the Brookhaven Linac Isotope Producer (BLIP) facility at BNL, the ESIPP at ORNL, and hot cell facilities for processing and handling irradiated materials and purified products at ORNL, BNL, and LANL. In addition, the DOE IP utilizes the capabilities of the Low Energy Accelerator Facility (LEAF) at ANL, the High Flux Isotope Reactor (HFIR) at ORNL, the INL Advanced Test Reactor (ATR), Pacific Northwest National Laboratory (PNNL) for processing and packaging strontium-90, the Y-12 National Security Complex for processing and packaging lithium-6 and lithium-7, the LANL Plutonium Facility for extracting americium-241 from NNSA plutonium processes, the Savannah River Site (SRS) for the extraction and distribution of helium-3, and the radioisotope separator at INL for nuclear forensic isotopes.

The DOE IP ensures National Preparedness or mission readiness for the production and processing of isotopes at this growing portfolio of production sites to provide domestic supply chains of critical isotopes not available commercially or domestically; the isotope production costs are paid by the customer. Operating and capital investments enable critical and compelling enhancements to production or processing capability, including recovery of valuable isotopes from legacy reactor targets (Mark 18-A); development of enrichment capabilities for heavier stable isotopes; the fabrication and assembly of enrichment technology. Scientists and engineers support the implementation of Food and Drug Administration (FDA) regulatory requirements for production of isotopes such as actinium-225 to enable their use in future or approved radiopharmaceuticals.

DOE IP operations of ESIPP at ORNL produce research quantities of enriched stable isotopes through the use of electromagnetic separation and centrifuge technology. The first campaign at ESIPP produced ruthenium-96 to provide the otherwise unavailable world-wide target material to the Relativistic Heavy Ion Collider (RHIC) for its planned physics program. ESIPP is now focused on production of ytterbium-176, currently only produced in Russia, needed for the production of no-carrier added (NCA) lutetium-177, which is used in a drug to treat prostate cancer. The DOE IP is expanding enriched stable isotope production capabilities with the implementation of the SIPF MIE and SIPRC line item construction project.

Some examples of produced isotopes are:

- actinium-225, actinium-227, tungsten-188, lutetium-177, strontium-89, strontium-90, and cobalt-60 for cancer therapy;
- americium-241 and californium-252 for oil and gas exploration and production well logging;
- bismuth-213, lead-212, astatine-211, copper-67, thorium-227, and radium-223 for cancer and infectious disease therapy and research; cadmium-109 for X-ray fluorescence imaging and environmental research;
- berkelium-249, americium-243, plutonium-242, californium-251, einsteinium-254, and curium-248 for use as targets for discovery of new super heavy elements;
- fermium-257 for heavy element chemistry research;

- selenium-75 for industrial radiography;
- silicon-32 for oceanography and climate modeling;
- ytterbium-171 for quantum memory;
- nickel-63 for explosives detection, and lithium-6 and helium-3 for neutron detectors for homeland security applications;
- promethium-147 for nuclear batteries; and
- arsenic-73, iron-52, and zinc-65 as tracers in metabolic studies.

It can take decades for an economically and technically viable commercial market to be formed 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 so as to not compete with the domestic industry. Recent examples include strontium-82 for cardiac heart imaging and germanium-68 for medical diagnostics in which domestic commercial production now exists.

Projects

The prototype capabilities of the ESIPP, developed through DOE IP-supported research, demonstrated the feasibility of new EMIS and GC technology and re-established a general enriched stable isotope production capability in the U.S. The SIPF MIE at ORNL received baseline approval in July 2020 and modestly increases GC production capability. The U.S. SIPRC line item construction project further expands GC production capability and significantly increases EMIS production capability to meet the Nation's growing demand for stable isotopes. SIPRC will mitigate the Nation's dependence on foreign countries for stable isotope supply. CD-0, Approve Mission Need, was received on January 4, 2019. The current Total Project Cost (TPC) point estimate is $250,000,000 with an updated preliminary TPC range of $187,000,000 to $338,000,000. Demand drivers include enriched stables isotopes for medical, national security and fundamental research projects. With support from the DOE IP, ORNL is advancing production capabilities for these stable isotopes, primarily EMIS and GC technologies. Electromagnetic isotope separators can separate isotopes for many elements to very high purity but at lower production rates, while gas centrifuge production cascades can produce much larger quantities of isotopes but are limited to those isotopes that have compatible feedstock chemicals.

Isotope R&D and Production
FY 2022 Research Initiatives

Isotope R&D and Production supports the following FY 2022 Research Initiatives.

(dollars in thousands)

	FY 2020 Enacted	FY 2021 Enacted	FY 2022 Request	FY 2022 Request vs FY 2021 Enacted
Biopreparedness Research Virtual Environment (BRaVE)	–	–	2,073	+2,073
Fundamental Science to Transform Advanced Manufacturing	–	–	1,000	+1,000
Quantum Information Science	–	–	4,300	+4,300
Reaching a New Energy Sciences Workforce (RENEW)	–	–	2,000	+2,000
Total, Research Initiatives	**–**	**–**	**9,373**	**+9,373**

Isotope R&D and Production
Funding

(dollars in thousands)

	FY 2020 Enacted	FY 2021 Enacted	FY 2022 Request	FY 2022 Request vs FY 2021 Enacted
Isotope R&D and Production				
Isotopes, Research	–	–	36,776	+36,776
Isotopes, Operations	–	–	41,224	+41,224
Subtotal, Isotope R&D and Production	**–**	**–**	**78,000**	**+78,000**
Construction				
20-SC-51, U.S. Stable Isotope Production and Research Center (SIPRC), ORNL	–	–	12,000	+12,000
Subtotal, Construction	**–**	**–**	**12,000**	**+12,000**
Total, Isotope R&D and Production	**–**	**–**	**90,000**	**+90,000**

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 needed to achieve federal missions, are in fact, available. Stable and radioactive isotopes are vital to the missions of many 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), NNSA, National Science Foundation (NSF), and other SC programs. The DOE IP conducts biennial Workshops on Federal isotope Supply and Demand to collect 5-year projections from all federal agencies across the USG complex to ensure adequate supply. The DOE IP participates in a number of Federal Working Groups and Interagency groups to promote communication, including the White House Office of Science and Technology Policy (OSTP) National Science and Technology Committee Subcommittee on Critical and Strategic Mineral Supply Chains, and the Interagency Group on He-3, which it leads and that reports to the White House National Security Staff. The DOE IP participates in the Certified Reference Material Working Group which ensures material availability for nuclear forensics applications that support national security missions. As a service, the DOE IP collects demand and usage information on helium-4 from the federal complex and provides it to the Bureau of Land Management (BLM) so that BLM can optimize their plans for the helium-4 Federal Reserve.

While the DOE IP is not responsible for the production of molybdenum-99, the most 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. Additionally, DOE IP participates in the international High-Level Group on the Security of Supply of Medical Isotopes lead by the Organization for Economic Co-operation and Development.

Program Accomplishments

Completion of Drug Master File Enables Advanced Clinical Trials for Cancer and Infectious Disease Therapy

Actinium-225 (Ac-225) has shown great promise as a highly effective radioisotope in pharmaceuticals being developed for the treatment of various cancers and infectious diseases such as COVID-19. For an isotope to be used in advanced clinical trials necessary for Food and Drug Administration (FDA) approval of these pharmaceuticals, production of actinium-225 must be compliant with stringent guidelines and regulatory requirements. In FY 2020, a Drug Master File (DMF) for the DOE Isotope Program's accelerator-produced actinium-225, which was submitted to the FDA, enabling its use by drug developers in advanced clinical trials and ultimately in approved drugs. In early FY 2021, a DMF was also submitted to the FDA for the actinium-225 derived from thorium-229. As required to assure the quality of the actinium-225, current Good Manufacturing Practices production was implemented for both routes; this was a substantial undertaking involving the establishment of dedicated infrastructure, the training of all personnel involved in the production process, and the development of dozens of procedures and quality control documents.

New Gas Centrifuge Cascade Completes First Production Campaign

The DOE IP team at ORNL has successfully re-established U.S. stable isotope enrichment with gas centrifuge technology by completing its first gas centrifuge campaign for molybdenum-100. Molybdenum-100 and -98 stable isotopes are alternative feedstocks for production of the radioisotope technicium-99m, a medical radiotracer diagnostic that is in short supply due to its extensive use in medical procedures around the world. ORNL operated the prototype gas centrifuge cascade in its ESIPP for many months to collect crucial mechanical reliability data and followed that with four months of gas operations that produced the enriched material.

DOE Isotope Program makes available new isotope for diagnosis and treatment of cancer and infectious disease

Routine production of the copper-67 radioisotope has been established at the ANL LEAF. The routine availability of clinically relevant quantities of copper-67 is enabling medical research and clinical trials to investigate the potential of copper-67 to treat cancers through targeted radiotherapy. Copper-67 falls in a unique category of isotope known as theranostics, or isotopes which allow for simultaneous therapeutic disease treatment and diagnostic imaging of a patient. A recent collaboration between researchers at ANL and the University of Iowa demonstrated the theranostic potential of copper-67 could be realized using existing clinical infrastructure, and without modification of the costly computer programs which interpret scans and provide diagnostic information (e.g. tumor location and size). The studies were conducted using clinical grade models of a human torso and demonstrate the cost-effective role isotopes play in personalized medicine.

New chemical separation system for rare-earth radio-isotope production

Rare earth elements (REE) are critical materials since their unique optical, electric and magnetic properties render them indispensable components in modern electronic and electrical devices. Techniques to foster independence from foreign suppliers include recycling of REE from spent electronic parts or other materials, which in turn require novel preparative and analytical separation systems. LANL prepared and evaluated a new chromatographic system based on solvent impregnated resins that enables the efficient and selective separation of REE from other chemical elements and from each other. This system can enable efficient and cost-effective production of rare earth radioisotopes such as lutetium-177 for cancer therapy and promethium-147 for radioisotope power sources for national security, space exploration, and industrial application.

Activities and Explanation of Changes

(dollars in thousands)

FY 2021 Enacted		FY 2022 Request	Explanation of Changes FY 2022 Request vs FY 2021 Enacted
Isotope R&D and Production	**$ —**	**$90,000**	**+$90,000**
Isotopes, Research	$ —	$36,776	+$36,776
Isotopes Research was under the Nuclear Physics program in the FY 2021 Enacted Appropriation with a funding level of $26,660,000. As part of the SC reorganization in FY 2020, a separate Office of Isotope R&D and Production was established.		The Request supports high impact R&D activities at universities and national laboratories leading to advanced, innovative, and novel isotope production and processing technologies, to increase the availability of isotopes in short supply and promote U.S. independence. A priority of the research program will be to continue R&D 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 translation to medical applications. The Request 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 a priority. Research to ensure National Preparedness in isotope production and availability support research efforts in partnership with the University of Missouri to address a single point failure in reactor isotope processing; simultaneously, conceptual design for the RPF is pursued to develop longer-term solutions to this challenge at ORNL. Research to advance isotope harvesting capabilities and expertise at FRIB are roughly maintained. The Request continues OPC for the SIPRC project.	Core research groups are initiated at ANL and INL, both of whom bring unique capabilities to the portfolio. The research group at ANL brings new core competence in isotope production using accelerator electron beams and the group at INL brings experience in the production of highly pure enriched radioisotopes for the nuclear forensics community using electromagnetic separation. Research activities aimed at the development of production approaches for isotopes of interest to next-generation QIS systems increase, as does support for National Preparedness to address a lack of reactor isotope processing expertise and capabilities, and for research to promote the translation of isotopes to medical applications, in coordination with NIH. Support for the DOE IP Traineeship Program with a goal to increase the diversity of the workforce continues in FY 2022.

(dollars in thousands)

FY 2021 Enacted	FY 2022 Request	Explanation of Changes FY 2022 Request vs FY 2021 Enacted
Isotopes, Operations $ —	$41,224	+$41,224
Isotopes Operations was under the Nuclear Physics program in the FY 2021 Enacted Appropriation with a funding level of $36,640,000.	The Request supports mission readiness of the growing portfolio of isotope production and processing sites and nurtures critical core competencies in isotope production and development, ensuring robust domestic supply chains so that isotope orders for cancer therapy and other commitments are reliably met. Support maintains NIDC activities to interface with the growing stakeholder community and rapidly expanding isotope portfolio. Funding will continue support of electromagnetic separation technology optimized to heavy elements, enriched radioisotope separation technology, extraction of valuable isotopes from legacy Mark 18-A targets, infrastructure for assembly and fabrication of stable enrichment components.	Increased support for stable isotope operations enable additional production campaigns on gas centrifuges and EMIS machines, and SIPF commissioning preparation. Increased support for accelerator reactor production and processing captures growth in production portfolios, particularly at LANL with increased efforts for alpha-emitting isotope production and ANL, that continues to ramp up copper-67 for clinical trials. Support increases for the new radio-isotope separations capabilities at INL for nuclear forensics. Activities related to QIS isotopes and FRIB Isotope Harvesting are moved to the Research subprogram.
Construction $ —	$12,000	+$12,000
The U.S. Stable Isotope Production and Research Center (SIPRC) was under the Nuclear Physics program in the FY 2021 Enacted Appropriation with a funding level of $12,000,000.	The Request will support the continuation of engineering design of the U.S. SIPRC and long lead procurements.	Progress continues in design of the U.S. SIPRC and long lead procurements to mitigate dependence on foreign supply of isotopes.

Isotope R&D and Production
Construction Projects Summary

(dollars in thousands)

	Total	Prior Years	FY 2020 Enacted	FY 2021 Enacted	FY 2022 Request	FY 2022 Request vs FY 2021 Enacted
20-SC-51, U.S. Stable Isotope Production and Research Center, ORNL						
Total Estimated Cost (TEC)	215,200	–	–	–	12,000	+12,000
Other Project Cost (OPC)	5,200	–	–	–	3,200	+3,200
Total Project Cost (TPC)	**220,400**	**–**	**–**	**–**	**15,200**	**+15,200**
Total, Construction						
Total Estimated Cost (TEC)	**N/A**	**N/A**	**–**	**–**	**12,000**	**+12,000**
Other Project Cost (OPC)	**N/A**	**N/A**	**–**	**–**	**3,200**	**+3,200**
Total Project Cost (TPC)	**N/A**	**N/A**	**–**	**–**	**15,200**	**+15,200**

Note: The total for the U.S. Stable Isotope Production and Research Center (SIPRC) of $220,400,000 does not include $29,600,000 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, is $250,000,000. This project is not baselined.

Isotope R&D and Production
Funding Summary

(dollars in thousands)

	FY 2020 Enacted	FY 2021 Enacted	FY 2022 Request	FY 2022 Request vs FY 2021 Enacted
Research	–	–	30,576	+30,576
Facility Operations	–	–	41,224	+41,224
Projects				
Line Item Construction (LIC)	–	–	18,200	+18,200
Total, Projects	**–**	**–**	**18,200**	**+18,200**
Total, Isotope R&D and Production	**–**	**–**	**90,000**	**+90,000**

Isotope R&D and Production
Scientific Employment

	FY 2020 Enacted	FY 2021 Enacted	FY 2022 Request	FY 2022 Request vs FY 2021 Enacted
Number of Permanent Ph.Ds (FTEs)	–	–	37	+37
Number of Postdoctoral Associates (FTEs)	–	–	31	+31
Number of Graduate Students (FTEs)	–	–	26	+26
Number of Other Scientific Employment (FTEs)	–	–	91	+91

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

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

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

Summary

The FY 2022 Request for the U.S. Stable Isotope Production and Research Center (SIPRC) is $12,000,000 of TEC funding and $3,200,000 of OPC funding. The current Total Project Cost (TPC) point estimate is $250,000,000 with an updated preliminary TPC range of $187,000,000 to $338,000,000 in preparation for CD-1 consideration.

Significant Changes

This project data sheet (PDS) is an update of the FY 2021 PDS; the project is not a new start in FY 2022. The most recent DOE Order 413.3B approved Critical Decision (CD) is CD-0, Approve Mission Need, which was approved on January 4, 2019. The project is working to achieve CD-1/3A, Approve Alternative Selection and Cost Range/Long Lead Procurement, planned for the fourth quarter FY 2021. The TPC point estimate and range are a result of advancing project maturity with the completion of conceptual design in preparation for CD-1/3A. In addition, the project advanced the overall project structure by adding one additional subproject (SP) for a total of three. SIPRC's three subprojects are as follows: 1) new facility and Electromagnetic Isotope Separator (EMIS) production capability; 2) centrifuge production capability for Molybdenum 100; and 3) centrifuge infrastructure in preparation for Silicon 28 production capability. FY 2022 funding will continue support for project engineering and design activities and planned long lead procurements, such as materials for known designs of technologies developed under previous projects. The prior projects referenced include the completed Enriched Stable Isotope Production Prototype (ESIPP) and the ongoing Stable Isotope Production Facility (SIPF) Major Item of Equipment.

A Federal Project Director (FPD) with certification level 3 has been assigned to the U.S. SIPRC.

Critical Milestone History

Fiscal Year	CD-0	Conceptual Design Complete	CD-1	CD-2	Final Design Complete	CD-3	CD-4
FY 2020	1/4/19	4Q FY 2020	4Q FY 2020	3Q FY 2022	2Q FY 2022	3Q FY 2022	4Q FY 2027
FY 2021	1/4/19	4Q FY 2020	4Q FY 2020	3Q FY 2022	2Q FY 2022	3Q FY 2022	4Q FY 2027
FY 2022	1/4/19	4Q FY 2021	4Q FY 2021	4Q FY 2025	4Q FY 2025	4Q FY 2025	1Q FY 2031

Note: CD-2, CD-3, and CD-4 dates are for the overall project and correspond to the latest subproject date for a given CD.

Critical Decision dates for SP-1, SP-2 and SP-3 are broken out below:

FY 2022[a]						
Subproject (SP)	CD-0	Conceptual Design Complete	CD-1	CD-3A	CD-2/3	CD-4
SP-1	1/4/19	4Q FY 2021	4Q FY 2021	4Q FY 2021	4Q FY 2023	4Q FY 2029
SP-2	1/4/19	4Q FY 2021	4Q FY 2021	3Q FY 2025	4Q FY 2025	1Q FY 2031
SP-3	1/4/19	4Q FY 2021	4Q FY 2021	1Q FY 2025	4Q FY 2025	2Q FY 2030

[a] The project is pre-CD-1. The estimated cost and schedule 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

Fiscal Year	Performance Baseline Validation	CD-3A	CD-3B
FY 2020	3Q FY 2022	4Q FY 2020	-
FY 2021	3Q FY 2022	4Q FY 2020	-
FY 2022	4Q FY 2023	4Q FY 2021	1Q FY 2023

CD-3A for Sub-Project 1 – Approve Long-Lead Procurements, (EMIS components)
CD-3B for Sub-Project 1 – Approve Long-Lead Procurements for Facility (Site preparations)

Project Cost History
This project is at CD-0 with an updated preliminary point estimate of $250,000,000 and Total Project Cost (TPC) range of $187,000,000 to $338,000,000. The point estimate has been refined as the previous rough order of magnitude estimate was matured in preparation for CD-1 approval. 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, D&D	OPC, Total	TPC
FY 2020	TBD	TBD	TBD	TBD	TBD	TBD	TBD
FY 2021	14,000	274,000	288,000	10,000	N/A	10,000	298,000
FY 2022	36,000	203,200	239,200	10,800	N/A	10,800	250,000

2. Project Scope and Justification

Scope
The scope of this project includes design and construction of a building and associated instrumentation and equipment for enriching isotopes. Electromagnetic isotope separator systems and gas centrifuge cascades will be designed and implemented in this new single 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 leveraged by existing designs developed from prior projects and R&D supported by the DOE Isotope Program (DOE IP). The laboratory is considering the optimal number of production systems for each type of technology as part of the alternatives analysis for Critical Decision-1 (CD-1).

Justification
SIPRC is critical to the Nation and to the DOE IP within SC's Office of Isotope R&D and Production. The facility will expand the U.S. stable isotope production capability to address multiple production capabilities of enriched stable isotopes to provide domestic supply chains of critical isotopes and mitigating U.S. dependencies on foreign suppliers. The current capacity within the United States is insufficient to meet the Nation's growing demands, and is spread out geographically

at ORNL in smaller buildings, which increases operating complexity, operating costs, and complicates security protection strategies. The SIPRC project will provide an adequately sized building to address our Nation's 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 is expected later in 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.

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 2020	12,000	12,000	–
FY 2022	9,000	9,000	11,500
Outyears	15,000	15,000	24,500
Total, Design (TEC)	**36,000**	**36,000**	**36,000**
Construction (TEC)			
FY 2021	12,000	12,000	–
FY 2022	3,000	3,000	13,600
Outyears	188,200	188,200	189,600
Total, Construction (TEC)	**203,200**	**203,200**	**203,200**
Total Estimated Cost (TEC)			
FY 2020	12,000	12,000	–
FY 2021	12,000	12,000	–
FY 2022	12,000	12,000	25,100
Outyears	203,200	203,200	214,100
Total, TEC	**239,200**	**239,200**	**239,200**

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Other Project Cost (OPC)			
FY 2019	500	500	171
FY 2020	2,100	2,100	2,429
FY 2021	3,000	3,000	3,000
FY 2022	3,200	3,200	3,200
Outyears	2,000	2,000	2,000
Total, OPC	**10,800**	**10,800**	**10,800**

(dollars in thousands)

	Budget Authority (Appropriations)	Obligations	Costs
Total Project Cost (TPC)			
FY 2019	500	500	171
FY 2020	14,100	14,100	2,429
FY 2021	15,000	15,000	3,000
FY 2022	15,200	15,200	28,300
Outyears	205,200	205,200	216,100
Total, TPC	**250,000**	**250,000**	**250,000**

4. Details of Project Cost Estimate

(dollars in thousands)

	Current Total Estimate	Previous Total Estimate	Original Validated Baseline
Total Estimated Cost (TEC)			
Design	27,000	12,000	**N/A**
Design - Contingency	9,000	2,000	**N/A**
Total, Design (TEC)	**36,000**	**14,000**	**N/A**
Construction	150,000	210,000	**N/A**
Construction - Contingency	53,200	64,000	**N/A**
Total, Construction (TEC)	**203,200**	**274,000**	**N/A**
Total, TEC	**239,200**	**288,000**	**N/A**
Contingency, TEC	*62,200*	*66,000*	***N/A***
Other Project Cost (OPC)			
R&D	2,600	N/A	**N/A**
Conceptual Design	4,000	2,600	**N/A**
Start-up	1,500	5,000	**N/A**
OPC - Contingency	2,700	2,400	**N/A**
Total, Except D&D (OPC)	**10,800**	**10,000**	**N/A**
Total, OPC	**10,800**	**10,000**	**N/A**
Contingency, OPC	*2,700*	*2,400*	***N/A***
Total, TPC	**250,000**	**298,000**	**N/A**
Total, Contingency (TEC+OPC)	***64,900***	***68,400***	***N/A***

5. Schedule of Appropriations Requests[a]

(dollars in thousands)

Request Year	Type	Prior Years	FY 2020	FY 2021	FY 2022	Outyears	Total
FY 2020	TEC	—	5,000	—	—	—	TBD
	OPC	500	—	—	—	—	TBD
	TPC	500	—	—	—	—	TBD
FY 2021	TEC	—	12,000	12,000	—	264,000	288,000
	OPC	500	2,100	—	—	7,400	10,000
	TPC	500	14,100	12,000	—	271,400	298,000
FY 2022	TEC	—	12,000	12,000	12,000	203,200	239,200
	OPC	500	2,100	3,000	3,200	2,000	10,800
	TPC	500	14,100	15,000	15,200	205,200	250,000

[a] The project does not have CD-1 or CD-2 approval; FY 2022 schedules and costs are estimates consistent with the updated preliminary point estimate.

6. Related Operations and Maintenance Funding Requirements

Start of Operation or Beneficial Occupancy	4Q FY 2027
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	54,000
Area of existing facility(ies) being replaced..	N/A
Area of any additional D&D space to meet the "one-for-one" requirement	N/A

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 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.