

Memorandum

DATE: April 7, 2011

REPLY TO

ATTN OF: IG-35 (A07FN003)

SUBJECT: Department of Energy Isotope Program's Fiscal Year 2007 Financial Statement Audit –
Audit Report No.: OAS-FS-11-06

TO: Director, Office of Science
Director, Facilities and Project Management Division, Office of Nuclear Physics

The attached report presents the results of the independent certified public accountants' audit of the United States (U.S.) Department of Energy Isotope Program's (the Program) Fiscal Year (FY) 2007 balance sheet and the related statements of net cost and changes in net position, and combined statement of budgetary resources for the year ended September 30, 2007 (hereinafter referred to as "financial statements").

The Office of Inspector General (OIG) engaged the independent public accounting firm of KPMG LLP (KPMG) to conduct the audit, subject to our review. KPMG is responsible for expressing an opinion on the Isotope Program's financial statements. In connection with the audit, KPMG also considered the Program's internal controls over financial reporting and performance measures and tested compliance with laws and regulations. The OIG monitored audit progress and reviewed the audit report and related documentation. This review disclosed no instances where KPMG did not comply, in all material respects, with generally accepted Government auditing standards. The OIG did not express an independent opinion on the Program's financial statements.

KPMG concluded that the Program's financial statements as of and for the year ended September 30, 2007, are presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. The auditors' consideration of internal control over financial reporting resulted in the following conditions being identified as significant deficiencies:

- A. Controls over Accounting for Inventory at Brookhaven National Laboratory;
- B. Improvements Needed in Financial Reporting;
- C. Unclassified Network and Information Systems Security;
- D. Accounting for Property, Plant, and Equipment; and,
- E. Accounting for Accounts Receivable at Oak Ridge National Laboratory.

Significant deficiencies A and B are considered to be material weaknesses. There were no deficiencies involving the design of the internal control over the existence and completeness assertions related to key performance measures.

The results of the auditors' tests of compliance with certain provisions of laws, regulations, contracts, and grant agreements disclosed no instances of noncompliance or other matters that are required to be reported herein under *Government Auditing Standards*, issued by the Comptroller General of the U.S., and Office of Management and Budget Bulletin Number 07-04, *Audit Requirements for Federal Financial Statements*.

We appreciate the cooperation of your staff during the audit.



Daniel M. Weeber
Director, Environment, Technology,
and Corporate Audits Division
Office of Inspector General

Attachment

cc w/attachment:

Director, Office of Financial Control and Reporting, CF-12
Director, Energy Finance and Accounting Service Center, CF-11
Assistant Director, Office of Risk Management, CF-80
Team Leader, Office of Risk Management, CF-80
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Isotope Program

Report and Financial Statements

Performance Measures
and Accomplishments

September 30, 2007



United States Department of Energy
Office of Nuclear Energy, Science and Technology

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Report and Financial Statements for Fiscal Year 2007

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**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Management's Discussion and Analysis

(Unaudited)

September 30, 2007

**U.S. Department of Energy Isotope Program
Fiscal Year 2007 Annual Report and Financial Statements,
Performance Measures and Accomplishments**

MANAGEMENT'S DISCUSSION AND ANALYSIS

Program Overview

The mission of the Isotope Program (the Program) in the Department of Energy (the Department or DOE) Office of Nuclear Energy (NE) is to maintain critical nuclear facilities in a safe, environmentally-compliant and cost-effective manner to provide continued reliable isotope production. These isotopes improve the accuracy and effectiveness of medical diagnoses and therapy, enhance homeland security, improve the efficiency of industrial processes, and provide precise measurement and investigative tools for materials, biomedical, environmental, archeological, and other research. The Program assures that facilities supported by NE meet essential safety and environmental requirements and are maintained at user-ready levels. Actual development, production, and other activities are funded by other DOE programs, by the private sector, or by other Federal agency users.

DOE applies its unique expertise and capabilities to address technology issues associated with the application, production, handling, and use of isotopes. Adequate supplies of medical and research isotopes, produced by either domestic or foreign sources, are essential to maintain effective diagnosis, treatment, and research capabilities in the United States (U.S.). For over 50 years, this program and its predecessors have been at the forefront of the development and production of stable and radioactive isotope products that are now used worldwide. The Department's work is the basis for the stable and radioactive isotopes used in the world today as part of a multibillion-dollar industry.

The Program reports to the NE Assistant Secretary and operates under a revolving fund established by the 1990 Energy and Water Appropriations Act (Public Law 101-101), as modified by Public Law 103-316. It allows prices charged for the Program's products and services to be based on production costs, market value, U.S. research needs, and other factors. The Program receives annual funding from the Radiological Facilities Management Unit to maintain and upgrade the infrastructure that is needed to assure continued reliable production, with the production costs borne by the customers.

Isotopes are atoms of an element that have the same atomic number, but different atomic masses. Isotopes are used for hundreds of vital research, development, biomedical, and industrial applications that benefit society every day. For example, strontium-82 and thallium-201 are used for medical imaging to diagnose diseases and injuries. Californium-252 is used in a variety of applications in cancer treatment research. Helium-

3 is used in neutron detectors. Hundreds of other highly valuable, but less well-known applications also depend on isotopes as a vital component.

Isotopes play key roles in the diagnosis and treatment of several types of cancer, such as leukemia, melanoma, prostate, and breast cancer, as well as heart disease, respiratory ailments, and other life-threatening illnesses. Each day, over 40,000 medical patients receive nuclear medicine procedures.

A nuclear medicine image, called a scan, can quickly show physicians how well an organ or system is functioning. Lung ventilation/perfusion imaging, for example, uses two radioisotopes to show how well the lung's respiratory and circulatory systems are working. The patient inhales xenon-133, a chemically inert gas and a beta emitter. Because it is a gas, it follows the same pathway as oxygen in the lungs. Technetium-99m, a positron emitter, is administered to the same patient intravenously. It follows the pathway of blood through the lungs. The emitted radiation is then detected with cameras and the lungs are imaged. Regions in the lungs where both isotopes are not detected indicate blocked passages in either the respiratory system or circulatory system, depending on which isotope is absent. This type of nuclear procedure has the advantage over more traditional, anatomical imaging techniques (magnetic resonance imaging [MRI] or Computed Axial Tomography [CAT], for example) in that the physiology of the organ or system is revealed.

Such nuclear procedures are among the safest diagnostic tests available. They save many millions of dollars each year in health care costs and enhance the quality and effectiveness of patient care by avoiding costly exploratory surgery and similar procedures. For example, it has been demonstrated that the use of myocardial perfusion imaging (similar to lung ventilation/perfusion imaging except only one radioisotope is used to observe the flow of blood in the heart) in emergency department chest pain centers can reduce duration of stay on average from 1.9 days to 12 hours with a simultaneous reduction in charges.

The Program's products and services are sold to over 20 countries. The Program produces isotopes only where there is no U.S. private sector capability or other production capacity is insufficient to meet U.S. needs. The Department encourages private sector investment in new isotope production ventures and is willing to sell or lease its existing facilities and inventories for commercial purposes.

Isotopes may be either stable or radioactive. Stable isotopes include those that do not decay or emit radiation, as well as naturally occurring radioactive isotopes (radioisotopes) that have very long half-lives and hence low radioactivity. Although stable isotopes occur in nature, many are quite rare and need to be enriched to useable levels. The Program produces and sells many radioisotopes that are produced in reactors through neutron absorption followed by radioactive decay or produced in accelerators by bombarding materials with charged atomic particles followed by radioactive decay. Some isotopes are extracted from the waste byproducts of the Department's weapons program and research activities.

Facilities used by the Program include reactors, hot cells, and accelerators. Radioisotopes originate from a variety of the Department's sites, including Oak Ridge National Laboratory (ORNL), Los Alamos National Laboratory (LANL), Idaho National Laboratory (INL), and Brookhaven National Laboratory (BNL). With the exception of helium-3, produced by Savannah River Site (SRS), all stable isotopes are processed, sold and distributed from ORNL. The Program pays a facility charge for space and services at these facilities, which are managed by other Department program offices.

The Program directs and oversees the production and sale of its products and services and provides fiscal and activity guidance to laboratory contractors based on the Isotope Program Plan. This plan is developed jointly by Headquarters, Operations Offices, and the National Laboratories and is updated each year. Because the Program is a user of the Department's facilities and operates similarly to the Department's Work-for-Others Program, facility decontamination and decommissioning costs, particularly legacy costs, are the responsibilities of the programs that operate the facilities. However, cleanup costs directly attributable to isotope processing are the responsibility of the Program. The Program's products and services are generally sold through the Isotope Business Office located at ORNL.

Performance Highlights

The Program continues to work toward the Department's *Strategic Theme 1: Energy Security* to promote America's energy security through reliable, clean, and affordable energy and *Program Goal: National Nuclear Infrastructure* to maintain and enhance the national nuclear infrastructure to meet the Nation's energy, environmental, medical research, space exploration and national security needs. The following performance highlights reflect actual performance toward meeting the Program's goal and targets.

Results for each performance target in fiscal year 2007 are included in the Performance Results section. Comparative data is also shown for the past three fiscal years.

FACILITY IMPROVEMENTS AND UPGRADES

BNL Facilities

Design, Fabricate and Install Shielding Upgrades



In fiscal year 2007 and continuing through January 31, 2008, BNL added one inch of additional steel shielding to the faces of hot cells 3,4,5, and 6 and added one inch of steel shielding around the ventilation ducting above the hot cells. This was necessitated by the increases in production quantities of strontium-82 and germanium-68 that significantly increase radiation levels outside of the processing hot cells and the hot cell ventilation ducting. The additional shielding was installed to maintain the radiation safety of hot cells 3-6 at the same level as newer hot cells 1 and 2.

Ongoing Maintenance and Repair

- In order to improve beam stability, new magnet power supplies for the Brookhaven Linac Isotope Producer (BLIP) beam line were procured in fiscal year 2006 and installed early in fiscal year 2007. The power supplies are now in use.
- Routine maintenance was performed on BLIP and hot cells as required.

LANL Facilities

Ongoing Maintenance and Repair

This includes the following items:

- General TA-48 hot cell maintenance and refurbishment, including repair of manipulators.
- Maintenance of TA-48 inter-cell train.
- Routine maintenance of the Isotope Production Facility (IPF) cooling skid, target control system, ion-exchange columns, and hot cells.

ORNL Facilities

Ongoing Maintenance and Repair

This project includes a large number of general routine hot cell and equipment surveillance and maintenance activities, including heating, ventilating, and air conditioning, cranes, transportation casks, instrumentation, and asbestos mitigation.

NEW PRODUCT AND TECHNOLOGY DEVELOPMENT

Improved Production Methods

Copper-67 Process Development

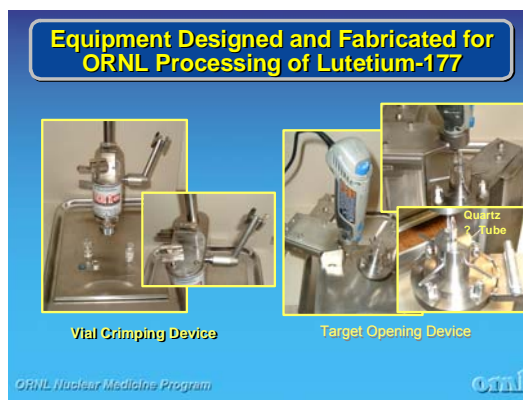
Because previously obtained levels of both yield and specific activity copper-67 were inadequate, it is necessary to develop new target types and chemistry to improve specific activity for labeling of antibodies for potential use in cancer therapy.

Beginning in fiscal year 2006, BNL examined the possibility of producing copper-67 by proton irradiation of natural zinc oxide target material. A series of cold blank runs were performed in order to determine sources of stable copper in the final copper-67 product that reduce the specific activity. The chemical reagents were determined and environmental sources in the hot cell were also investigated. Although small amounts of copper were measured, their contribution did not explain the final low product specific activity. The cause is, therefore, the direct production of stable copper-63 and -65 from the natural zinc target material. Theoretical calculations using the MCNPX code confirmed that direct nuclear production of copper-63 and -65 is significant. A high purity enriched zinc-68 target containing minimal other zinc isotopes was identified as the only feasible path forward, because it could significantly suppress the production of undesirable stable isotopes.

In fiscal year 2007, the effort continued and emphasized the design of a small target with expensive zinc-68 to try to improve the specific activity. To achieve an affordable production process, the chemical processing also must recover the residual zinc-68 and convert it back to a form suitable for reuse in a new target, which then must be filled, and sealed under vacuum remotely in a hot cell. The new prototype target failed leak testing due to inadequate metal C ring design. Modified silver coated stainless steel O-ring seals will be tried in fiscal year 2008. In order to use remaining BLIP beam time, the prototype target was electron beam welded without seals and a test irradiation performed. The copper-67 yield and specific activity were measured and appear promising. A new electrolytic cell was fabricated and electroplating techniques of zinc onto titanium was developed.

Lutetium-177 Process Development

The first lutetium-177 ORNL production campaign began in July 2005 and focused on the production, processing and distribution of High Flux Isotope Reactor (HFIR)-produced high specific activity lutetium-177. Although the peptide radio-labeling yields were reduced, presumably because of the presence of iron or other metallic impurities in this preparation, the lutetium-177 specific activity was confirmed by Inductively Coupled Plasma (ICP) analysis to exceed 60 Ci/mg



lutetium. In fiscal year 2006, ORNL examined the possibilities of producing lutetium-177 by proton irradiation of tungsten, tantalum and hafnium targets. The tungsten route was eliminated because of the very low cross-sections. Irradiations of tantalum and hafnium foils at both 100 and 200 million electron volt (MeV) were performed, but in both cases yields were low and the radio-purity was poor. The major isotopes produced were lutetium-171 and lutetium-172, not lutetium-177.

Continuation of the development of high specific activity lutetium-177 was delayed until fiscal year 2007 because the ORNL HFIR was not in operation during the February 2006 – May 2007 period and the Hot Cell C in Building 4501 was being renovated and equipped. A sample of enriched lutetium-176 was irradiated in early September 2007 in the HFIR. This target was processed at ORNL and samples of lutetium -177 were provided to several collaborators for analysis. Tests on radio-labeling using this material were quite satisfactory with no problems with any extraneous metals that could bind to a dodecane tetraacetic acid (DOTA) derivative. However, the lutetium-177 specific activity was approximately 25 percent of what was predicted for this target. Initial indications are that the hydraulic target may have not inserted properly resulting in either a lower flux or shorter irradiation time than expected. Additional targets were irradiated in November 2007 to determine optimal irradiation times (to minimize burn-up of lutetium-177) and to provide additional samples to researchers.

The therapeutic radioisotope lutetium-177 remains a potentially important isotope product and ORNL can possibly produce large quantities of high specific activity material at a moderate cost.

Determination of Phosphorous-32 and Phosphorous-33 in RbCl Irradiations

This LANL project, started in fiscal year 2005, was to determine the amounts of phosphorous-32 and phosphorous-33 produced as byproducts in the irradiation of rubidium chloride for strontium-82 production. The phosphorous-32 and phosphorous-33 are significant drivers of the “sum of fractions” that determines the nuclear facility categorization of the 100 MeV IPF and the TA-48 hot cells. A more accurate determination of these quantities will allow a better optimization of the strontium-82 production.

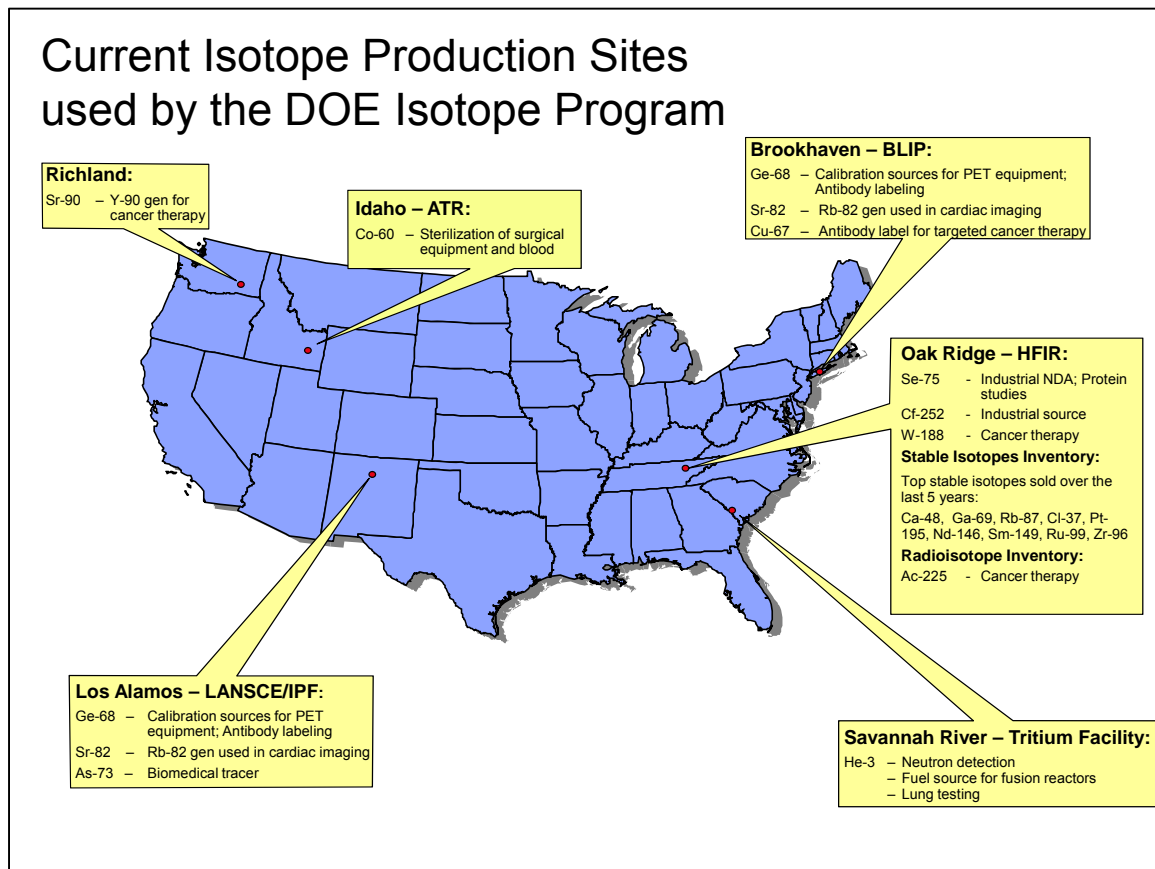
Work to perform the chemistry to separate the phosphorus fraction from the solution matrix in order to achieve good phosphorous assays was started in the last quarter of fiscal year 2005 and was completed in fiscal year 2006. Based on this work, a decision was made by the Department in late 2006 to exempt phosphorous-32 and phosphorous-33 from the amount of nuclear material allowed in TA-48, because it is a byproduct and not separated during the out process. The TA-48 hot cells have been operating under this exemption throughout 2007.

Development of Yttrium-86 as a New Isotope Product

This BNL project is to develop yttrium-86, a 14.7 h half-life positron emitter which can be used for PET imaging prior to cancer immunotherapy with yttrium-90. Yttrium-86 labeled tumor-seeking monoclonal antibodies (Mab) can be used for evaluating effective

tumor uptake and radiation dose, allowing patient-specific dosimetry for a subsequent administration of yttrium-90 labeled Mab for cancer radiotherapy. To make this product affordable, the expensive enriched strontium-88 target material must be recovered and reused in a new target, in the same manner as described for copper-67. The project consists of the design and fabrication of a new zirconium target that can be remotely fabricated and sealed in a hot cell when using recycled target material, developing new process chemistry, and measuring yttrium-86 yield and purity.

In fiscal year 2007, the new prototype target failed leak testing due to inadequate metal C ring design. Modified silver coated stainless steel O ring seals will be tried in fiscal year 2008. In order to use remaining BLIP beam time in fiscal year 2007, a target was sealed by electron beam welding and irradiated for one hour. Yttrium-86 was successfully separated chemically and the yield, radiopurity and specific activity measured. The yield was very high, indicating that a much shorter irradiation time may be adequate. Additional radiopurity and specific activity measurements will follow irradiation of prototypic enriched strontium-88 target material in fiscal year 2008.



PROGRAM COLLABORATION

The Department seeks cooperative isotope supply agreements with other government, private sector, and university isotope manufacturers, both domestic and foreign, to increase the Department's ability to meet customer requests by improving product

availability and reliability. For example, in fiscal year 2007, the Department continued to cooperate with the Institute for Nuclear Research (INR) in Troitsk, Russia, and iThemba LABS in Faure, South Africa on the production and supply of isotopes.

In fiscal year 2005, the Program and Missouri University Research Reactor (MURR) signed a Memorandum of Understanding (MOU). The MOU outlines a collaborative supply arrangement between the Program and MURR regarding short-lived reactor-produced isotopes. The goal of the MOU is to provide a stable supply of short-lived radioisotopes to the research community. A lutetium-177 target was irradiated at the HFIR and then shipped to MURR for chemical processing and distribution. This trial irradiation may lay the groundwork for future collaborative production and distribution of this and other isotopes. Future shipments of additional lutetium-177 to a number of possible research and development collaborators are planned for fiscal year 2008.

PROGRAM PLANNING

Since 1998 the Program has developed and annually updated a program plan to communicate the goals, objectives, strategies, and supporting activities established by the Program managers, as well as the key milestones and performance indicators used to measure the Program's success. The updates of the Isotope Program Plan incorporate site-specific information corresponding to the Program's targets and goal. In May of each year, the production sites also develop site-specific plans to complement the Isotope Program Plan.

Long-Range Use and Needs Planning

The Program is working to address its customers' requirements and to forecast future trends. This is being done through frequent interactions between customers and Program staff; data obtained from site visits and attendance at society exhibitions (e.g., the Society of Nuclear Medicine); and coordination of isotope activities with stakeholders in the isotope community, including other Federal agencies. Research on market sizes, pricing considerations, foreign suppliers, and customer feedback also is being obtained through independent surveys and studies, as well as Program management assessments.

Privatization

The Program adheres to the March 9, 1965 policy statement contained in the Federal Register regarding privatization. The Program has had several successful privatization initiatives and will continue to entertain divesting itself from production activities if assumed by private producers.

Transportation Status and Planning



The Program continues its activities to ensure an adequate fleet of shipping casks to carry a variety of product radioisotopes. In September 2005, the Program completed a

comprehensive review of the current shipping cask inventories at the production sites and evaluated these against anticipated requirements in the near term and over the next five to ten years. The Program either owns or has the use of 23 different kinds of Type A containers and seven different kinds of Type B containers. Type B containers are used to transport materials with levels of radioactivity larger than permitted in a Type A container per the Code of Federal Regulations (CFR) rule 10 CFR 71. Most of the containers are reusable, and the most commonly used non-reusable Type A containers can be purchased commercially whenever the supply is depleted.

The following fiscal year 2007 activities to augment the present container inventory and to improve the Program's capability to make future shipments in a more cost efficient manner are listed below.

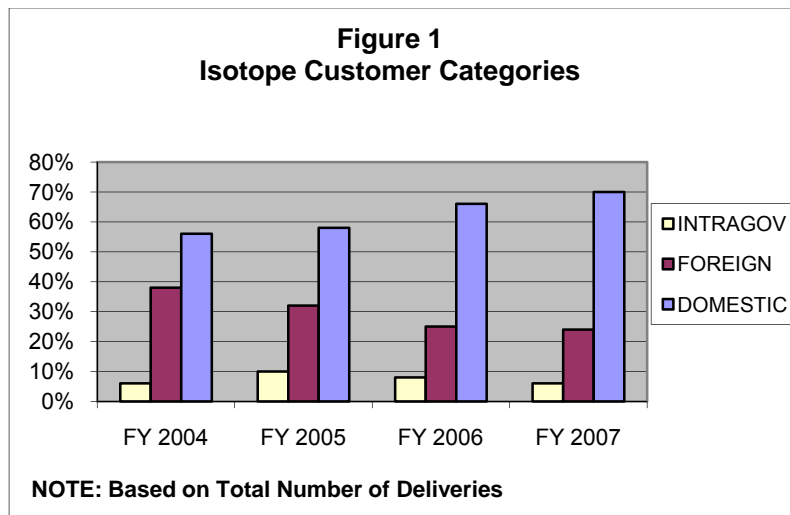
1. In 2005, a Department of Energy B (U)-96 Certificate of Compliance (CoC) was obtained for a Safeshield Model 2999A for use at the LANL IPF. In 2006, a purchase order was placed to fabricate and deliver a Safeshield 2999A in 2007. The original delivery date was scheduled for July 9, 2007. Welding problems on the flask, however, have resulted in parts having to be remade to meet quality assurance requirements. The delivery date has been extended to December 31, 2008.
2. To complement the new Croft Safeshield 2999A container listed above, extra spare parts were purchased to facilitate operation and maintenance in accordance with regulatory requirements contained in the Safety Analysis Report for Packaging.
3. Ten steel drums for the 62 pound LANL strontium shipping containers were purchased and delivered in fiscal year 2007. The original drums were damaged beyond repair. The new drums are supplied with Type A Class II Grade 60 neoprene gaskets, Celotex fiberboard shock absorbing material, and drum closing devices.
4. The Program initiated the extension of the Croft 2799E shipping container licenses in the United Kingdom, and revalidation certificates from the US Department of Transportation were requested. These containers allow for domestic shipments of Type B quantities of americium-241 and other radioactive isotopes from LANL. Delivery is expected in fiscal year 2008.

The program is considering production of isotopes, primarily cobalt-60 and cesium-131, at the Advanced Test Reactor (ATR), located at the Idaho National Laboratory. If production is resumed, a transportation review will be conducted to see whether the current inventory of containers at ATR would be sufficient or new containers would be needed. Depending on an arrangement between the Program and the Department's Idaho Operations Office, irradiated targets may be required to be transported to other sites or customers without using the hot cell.

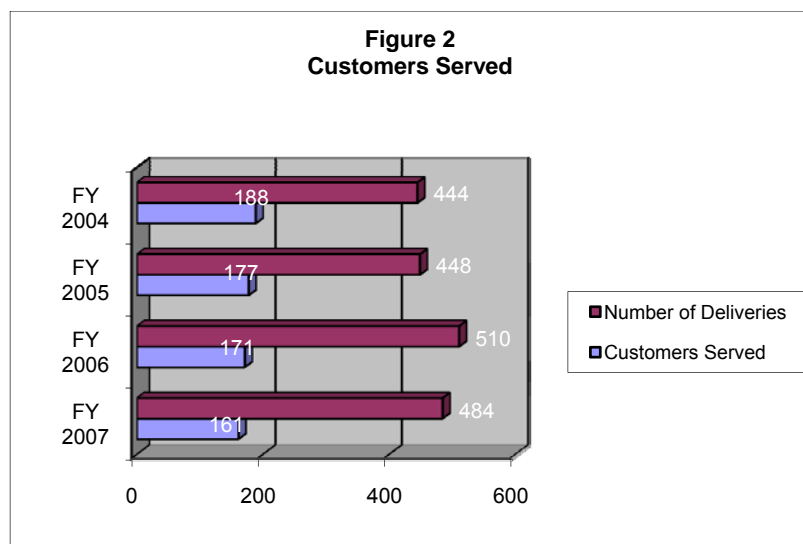
CUSTOMER SERVICE

The Program serves hundreds of customers, including major pharmaceutical companies such as General Electric (GE) Healthcare and Medactinium, Inc.; industrial users such as Spectra Gases and Frontier Technology; and hundreds of researchers at hospitals, national laboratories, universities, and private companies. Of the many isotopes produced and sold by the Program, less than ten are primary revenue producers. The remaining are research isotopes. In fiscal year 2007, eight customers provided about 84 percent of Program revenues.

The Program served over 160 customers in fiscal year 2007. Shipments totaled 484. Of these 484 deliveries, 339 were domestic, 117 were foreign, and 28 were intragovernmental (Figure 1). Comparative data over the last four years shows a small increase in domestic customers and corresponding decrease in foreign customers.



In fiscal year 2007 the Program achieved 98 percent on-time deliveries out of 484 shipments. Figure 2 reflects the results since fiscal year 2004. Results in all years presented met the Program's planned performance measures for on-time customer deliveries.



On-time Deliveries: FY 2004 = 96%; FY 2005 = 97%; FY 2006 = 96%; FY 2007 = 98%.

The variability in number of customers served and deliveries made was influenced by internal and external factors such as production and processing cycles, demand, batch costing policy and competition. Customer satisfaction with product specifications continues to be high. In fiscal year 2007, the Program ensured 99.8% of products and services provided met the terms of the contract/sales order. One customer stated the product received was not within the specifications required for its intended use. After further analysis, a replacement shipment was made. Compliments include an expression of appreciation from a customer for the extra effort made by laboratory staff to provide prompt delivery of several sources needed for use in the analysis of coal.

Financial Performance

The Program is audited consistent with the Chief Financial Officers Act of 1990 and the Government Performance and Results Act of 1993. Because of challenges related to the Department's fiscal year 2005 implementation of the new Standard Accounting and Reporting System, a balance sheet audit was conducted in fiscal year 2006. This year's audit includes the balance sheet and related statements of net costs, changes in net position, and budgetary resources.

PROGRAM REVENUES

Generally, program sales projections are dynamic and require frequent modification. However, actual sales for fiscal year 2007 were similar to the projection of \$15 million. This is primarily due to predictable quantities associated with existing contracts. In terms of revenue, radioisotopes outsold stable isotopes by a 2.74 to 1 ratio. Accelerator-produced isotopes outsold reactor-produced isotopes by a 2.43 to 1 ratio due to increased sales of accelerator-produced strontium-82 and germanium-68 and decreased reactor-produced isotope sales because of HFIR downtime to install a new cold source. Program

sales since fiscal year 2002 and sales projections through fiscal year 2009 are shown in Figure 3.

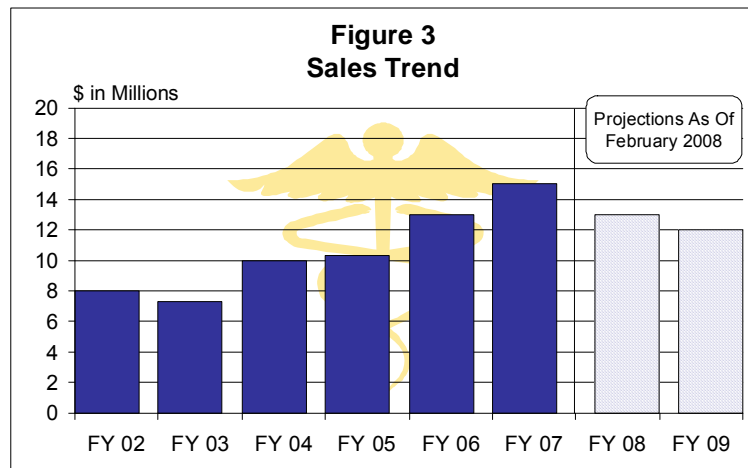
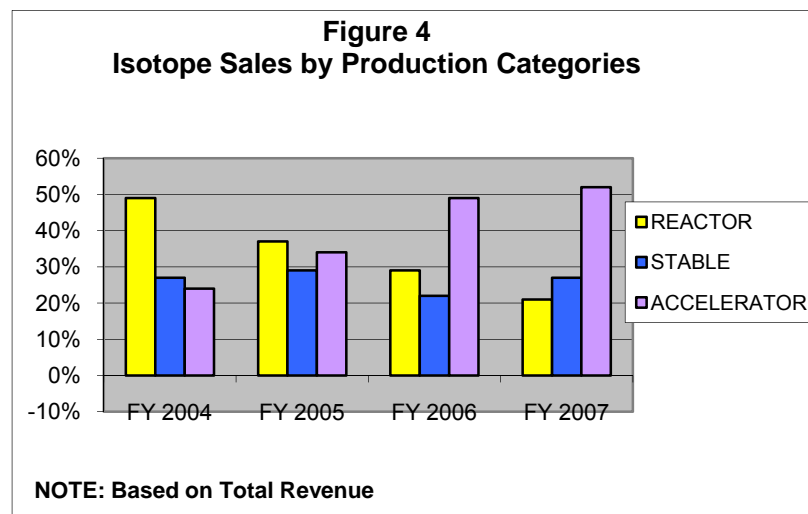


Figure 4, Isotope Sales by Production Categories, shows that sales of accelerator-produced isotopes comprised the highest percentage of the Program sales in fiscal year 2007, followed by stable isotopes, and reactor-produced isotopes. The recent percentage increase in the accelerator production category was due to strontium-82 and germanium-68 sales. This trend is projected to continue for another year.



To increase sales and reduce unit production costs, the Program will continue seeking high volume, multi-year contracts with customers. In addition, the Program will seek economies of scale such as increasing target yields which will result in lower unit cost.

FISCAL YEAR 2007 NET COST OF OPERATIONS

Net cost of operations for the Program during fiscal years 2007 and 2006 is summarized by the following activities:

	<u>FY 2007</u>	<u>FY 2006</u>
Exchange revenues	\$ <u>16,069,592</u>	<u>13,386,550</u>
Production and related facilities cost	19,907,972	14,591,245
Excess quantity revaluation	147,605	151,054
Lower of cost/market revaluation	<u>(22,317)</u>	<u>1,515,464</u>
Cost of goods sold	<u>20,033,260</u>	<u>16,257,763</u>
Gross loss	<u>3,963,668</u>	<u>2,871,213</u>
Depreciation expense	736,778	684,434
Bad debt expense	-	1,058
Infrastructure maintenance expense	4,151,655	3,520,308
Process development expense	437,002	256,099
Research grant expense	-	100,000
Technical services expense	750,693	446,284
Storage and distribution expense	136,525	222,291
General & admin. expense	895,578	620,466
Imputed costs	1,001,657	-
Program direction	<u>1,001,214</u>	<u>829,862</u>
Operating expense	<u>9,111,102</u>	<u>6,680,802</u>
Net cost of operations	\$ <u><u>13,074,770</u></u>	<u><u>9,552,015</u></u>

The major elements of the Program's net cost of operations include exchange revenues, cost of goods sold, and operating expenses. The overall net cost of operations in fiscal year 2007 increased almost 37% from fiscal year 2006. An analysis of changes in the net cost of operations from fiscal year 2006 to fiscal year 2007 disclosed significant changes in certain components of cost of goods sold and operating expenses. A large change in production and related facilities costs due to increased sales was the principal driver in the approximately 23% increase in cost of goods sold from FY 2006 to FY 2007. Los Alamos National Laboratory had the biggest cost increase during fiscal year 2007. Operating expenses increased about 36% from fiscal year 2006 to fiscal year 2007, principally due to increases in infrastructure maintenance expense and technical services expense. Infrastructure maintenance expense basically increased due to unanticipated equipment repairs needed to meet isotope production schedules at the IPF. Technical services expense increased mostly due to a growth in services provided for byproduct material over fiscal year 2006. In addition, the Program did not record imputed costs in fiscal year 2006.

FISCAL YEAR 2007 FINANCIAL STATEMENTS

The balance sheet presents the Program's assets, liabilities and net position. Significant changes from fiscal year 2006 to fiscal year 2007 resulted in an increase of approximately 23 percent in fund balance with Treasury due to growth in sales of strontium-82, germanium-68 and helium-3.

The statement of net cost summarizes the Program's operating costs by the isotope production and infrastructure categories. All operating costs reported reflect full costs, including all direct and indirect costs, consumed by the Program. Significant increases from fiscal year 2006 to fiscal year 2007 reflect higher sales volume.

The statement of changes in net position identifies appropriated funds used as a financing source for the Program. This statement presents the accounting events that caused changes in the net position section of the balance sheet from the beginning to the end of the reporting period. Increases from fiscal year 2006 to fiscal year 2007 are due to a larger federal contribution.

The statement of budgetary resources identifies the Program's budget authority. Budget authority is the authority that Federal law gives to agencies to incur financial obligations that will eventually result in outlays or expenditures. The increase of approximately 25 percent in budgetary resources from fiscal year 2006 is due to previous fiscal year funds not available to spend until fiscal year 2007 and an increase in collections due to greater sales and a larger federal contribution. The increase of approximately 35 percent in outlay disbursements from fiscal year 2006 to fiscal year 2007 is also due to funding provided for additional dedicated production runs, planned process development activities, and support for a new contractor-based isotope program.

Management Challenges and Significant Issues

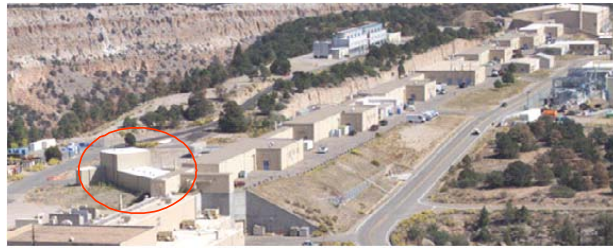
STRATEGIC PROGRAM OUTLOOK

The Department's policy is to transfer commercially attractive isotope production activities and sales to the private sector by offering to sell or lease existing facilities, equipment and material for commercial purposes or through the licensing of new patent technologies. Over the last several years, the Program has had a number of successful privatization ventures and will continue to seek commercial activities.

DOE isotope production depends primarily on reactors, accelerators, and hot cells operated by the Department for other missions. The Program's principal goal is to provide a reliable year-round supply of a wide range of radioisotopes, primarily in small quantities, at reasonable costs and on schedule.

The IPF, a new production capability at LANSCE, has played an important role in enabling year-round production of accelerator-produced isotopes, including many that are not typically available elsewhere. These medical isotopes will provide for the continuation of human clinical trials and future advancement of nuclear medicine applications.

**LANSCE Accelerator Complex-
Isotope Production Facility**



UNCLASSIFIED



At the present time, for reactor-produced isotopes, the Program is planning to use HFIR at ORNL and possibly the ATR at INL. To enhance the Department's production, cooperative production agreements are being negotiated with domestic and foreign facilities. For the long-term, the Nuclear Energy Research Advisory Committee (NERAC) has recommended the use of a dedicated reactor.

With the recent approval by the U.S. Food and Drug Administration of a therapeutic radio-labeled antibody, the National Cancer Institute and the Society of Nuclear Medicine have estimated that there will be a dramatic increase in research use of medical isotopes. Similarly, the need for isotopes used in homeland security and environmental applications is also increasing. The Program's production capability will ultimately be needed for initial ramp-up of production of major new isotope products until market forces bring in private producers.

INSPECTOR GENERAL REPORT

Inspector General (IG) Report DOE/IG-0709, *Management of the Department's Isotope Program*, was issued November 17, 2005. The report concluded that the Department had not always provided researchers with the isotopes needed to conduct planned research. Four Management Decision recommendations issued April 11, 2006 were completed by the end of December 2007.

As a result of one recommendation, the Program considered the conclusions of the September 2007 report by the National Research Council, of the National Academies, study committee on "Advancing Nuclear Medicine Through Innovation". The study addressed impacts of shortages of isotopes, highly trained radio chemists, and medical research among other topics. The report had several findings and five recommendations which included the need for the DOE to improve domestic medical radionuclide production and coordination among DOE Offices of Science (SC), NE, and the National Institutes of Health (NIH). NE has been meeting with SC and the NIH National Cancer Institute to discuss isotope supply, future partnerships, and other topics.

ISOTOPE PROGRAM TRANSFER

The Department's FY 2009 Congressional Budget Request states its intention to transfer the Program from the NE to SC's Office of Nuclear Physics (NP). Under NP, the Program will be renamed and reformed as the Isotope Production and Applications Program. The request provides additional funds for the development and production of research isotopes for the entire research community. NE will continue to have management responsibility for the Program until the transfer is signed into law.

In addition, over the last several years the Federal staff for the Program was reduced from seven to two people. To ensure uninterrupted operation of the Program through fiscal year 2007, a contractor-based isotope program was implemented. Two new contractor positions (Scientific Director and Program Manager) were created to provide overall scientific and program management leadership and support to the Program. Oversight and direction of the contractor-based program continues to come from the Program.

Over the next several years, NP will need to address several issues associated with the program transfer. The NP program will have the challenge to structure, organize and staff a team of personnel with appropriate skills to oversee the transition process, develop implementation strategies and provide leadership for the overall management of the program.

Financial Statements Limitations

The accompanying financial statements report the financial position and results of operations of the Program. The statements were prepared using the Program's accounting books and records in accordance with U.S. generally accepted accounting principles and the formats prescribed by the Office of Management and Budget (OMB). Although these statements are prepared from the same books and records, they are different from the financial reports used to monitor and control budgetary resources.

The statements should be read with the realization that they are for the Department's purposes, and that payment of all liabilities other than for contracts can be abrogated by the Program.

Systems, Controls and Legal Compliance

The Program is not required to report on compliance with the Federal Financial Management Improvement Act (FFMIA). However, because the Program is a user of Departmental systems, we noted that the Department has determined it was substantially compliant with FFMIA in fiscal year 2007. In response to Federal Managers' Financial Integrity Act (FMFIA) reporting, no material weaknesses in financial system internal controls were identified by the Department in fiscal year 2007.

The Program has no instances of non-compliance with any other laws, regulations, contracts, and grant agreements that had a direct and material effect on the determination of financial statement amounts in fiscal year 2007.

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Performance Results

(Unaudited)

September 30, 2007

PERFORMANCE RESULTS

The Program reports to the Office of Nuclear Energy Assistant Secretary and is a component of Radiological Facilities Management. To support the Department's Strategic Plan Strategic Theme 1, *Energy Security* and Strategic Goal 1.2, *Environmental Impacts of Energy* and NE's Government Performance and Results Act (GPRA) Unit 17 goal, *Maintain and Enhance the Nation's Nuclear Infrastructure Capability*, Radiological Facilities Management developed the performance measure discussed below. As part of Radiological Facilities Management, the Isotope Program developed the related targets to ensure a reliable supply of medical, research, and industrial isotopes to satisfy customer needs, address key planning assumptions, and meet future challenges.

Performance Measure: Maintain operability of Radiological Facilities Management and Idaho Facilities Management-funded facilities to enable accomplishment of Nuclear Energy, other DOE and Work-for-Others milestones by achieving a Facility Operability Index of 0.9.

Facility Operability/Availability is defined as either the facility is operating, producing and distributing isotope products or services or the facility is fully functional and could produce and distribute isotope products or services if required by mission needs. The program-related annual targets to track performance are listed below.

Commentary: The main focus is to maintain isotope facilities in a safe and environmentally compliant condition for the production and distribution of isotopes and related services. The continued availability of Department facilities used by the Program will be a focus of the Program over the next several years. The Program has encountered difficulty with proton beam availability and with reactor operating schedules. The Program will continue to work with the Department's organizations that manage the facilities in an effort to increase the availability of facilities for isotope production.

Another aspect is to provide a reliable supply of quality products and services based on customers' needs. Often, the quality of a product is more important to the customer than the price of the product. The credibility of the Program as a reliable isotope supplier is influenced greatly by the quality of the product supplied on a timely basis. The production sites apply quality assurance and control procedures to the production of their products. These procedures usually evolved from existing laboratory procedures. In some instances, international quality standards have been applied. As a means to ensure that the Program consistently provides its customers with high-quality products, the Program has developed and issued an Isotope Quality Plan to be used by the production sites to maintain and improve quality across all sites.

Overall Assessment: The annual targets focus on essential infrastructure and associated activities that represent key indicators critical to maintaining an effective infrastructure. Successful achievement of these targets represents an assurance that the Department's unique nuclear isotope infrastructure, required for a reliable supply of isotope products, services, and related technology, is available to support national priorities.

Completeness and reliability of performance data is documented by formal monthly reporting of scope (technical), schedule, and cost performance against program baselines established to meet the Program's objectives and performance targets. There are also a number of external reviews and audits that are conducted to evaluate progress. In addition to the financial audit performed by an independent certified public accountant contracted by the Office of Inspector General, the U.S. Food and Drug Administration and private companies review the Program's procedures and practices against Good Laboratory Practices, Good Manufacturing Practices, and industry standards and norms.

FY 2007 Annual Targets

Target 1: Meet production schedules within 10% variance (number of batches).

Commentary: The fiscal year 2007 target was met. To meet the customer requirements for delivery of specified quantities, actual planning is made on a real-time basis considering the customer requirements and the actual availability of irradiation and processing facilities. The Program successfully completed unprecedented operations of IPF and BLIP in a several week dedicated mode for the production of accelerator isotopes in fiscal year 2007. The operations were within schedule and met customer needs. All production schedules were met within the 10% variance.

Future Plans: This target will continue to be tracked in fiscal year 2008 to ensure availability of irradiation and process facilities to meet customer requirements. The Program will continue to maintain its production schedule within 10% variance. The Program will evaluate this target to determine if revisions will be required for the proposed transfer to the Office of Science in fiscal year 2009.

Documentation: Cost, Schedule and Performance Reports corroborated by monthly teleconferences with ORNL, LANL and BNL.

Related Prior Year Target 1 Performance:

FY 2006	FY 2005	FY 2004
Met target	Met target	Met target
Meet production schedules within 10% variance.	Meet production schedules within 10% variance.	Meet production schedules within 10% variance.

Target 2: Maintain on-time maintenance schedule with no more than 15% slip and revise annually.

Commentary: The fiscal year 2007 target was met. All routine maintenance was completed on schedule. Maintenance needs and upgrades of the facilities are reviewed annually. During this process, the infrastructure needs are evaluated in response to new Departmental priorities or policies.

Future Plans: This target will continue to be tracked in fiscal year 2008 to ensure routine maintenance is completed on schedule. The Program will continue to maintain on-time maintenance schedule with no more than 15% slip. The Program will evaluate this target to determine if revisions will be required for the proposed transfer to the Office of Science in fiscal year 2009.

Documentation: Cost, Schedule and Performance Reports corroborated by monthly teleconferences with ORNL, LANL and BNL.

Related Prior Year Target 2 Performance:

FY 2006	FY 2005	FY 2004
Met target	Met target	Met target
Maintain on-time maintenance schedule with no more than 15% slip and revise annually.	Maintain on-time maintenance schedule with no more than 15% slip and revise annually.	Maintain on-time maintenance schedule with no more than 15% slip and revise annually.

Target 3: Achieve cumulative variance of less than 10 percent from maintenance cost baseline for facility infrastructure.

Commentary: The fiscal year 2007 target was met. Overall cumulative year-to-date cost variance is +1.0 percent (cost underrun). Although the Program met its target, site-specific data indicated that LANL's cumulative cost variance was -9.0 percent (cost overrun). This was due to unanticipated repairs to the LANSCE and under-estimated infrastructure costs associated with dedicated production runs. The Program continues to plan for efficient and cost-effective facility and infrastructure use through its facility planning process.

Future Plans: This target will continue to be closely tracked in fiscal year 2008 to ensure a cumulative cost variance of less than 10 percent for facility infrastructure. The Program is making adjustments to prevent antideficiency violations and will continue to track monthly cost and performance reports to ensure that each laboratory is being managed and executed in accordance with its established baselines. The Program will continue to achieve cumulative variance of less than 10 percent from maintenance cost baseline for facility infrastructure. The Program will evaluate this target to determine if revisions will be required for the proposed transfer to the Office of Science in fiscal year 2009.

Documentation: Cost, Schedule and Performance Reports corroborated by monthly teleconferences with ORNL, LANL and BNL.

Related Prior Year Target 3 Performance:

FY 2006	FY 2005	FY 2004
Met target	Met target	Met target
Achieve cumulative variance of less than 10 percent from maintenance cost baseline for facility infrastructure.	Achieve cumulative variance of less than 10 percent from maintenance cost baseline for facility infrastructure.	Achieve cumulative variance of less than 10 percent from maintenance cost baseline for facility infrastructure.

Target 4: Maintain an average on-time delivery rate of 97% for stable isotopes and 95% for radioisotopes (95% overall).

Commentary: The fiscal year 2007 target was met. The Program met 98% overall on-time deliveries out of 484 shipments. Compared to fiscal year 2006, the overall achievement was 2% higher. The Program will continue to track deliveries to identify any significant issues.

Future Plans: This target will continue to be tracked in fiscal year 2008 to ensure an overall on-time delivery rate of 95%. The Program will continue to achieve an average on-time delivery rate of 97% for stable isotopes and 95% for radioisotopes. The Program will evaluate this target to determine if revisions will be required for the proposed transfer to the Office of Science in fiscal year 2009.

Documentation: Cumulative Business Results to Date report corroborated by monthly teleconferences with ORNL, LANL and BNL.

Related Prior Year Target 4 Performance:

FY 2006	FY 2005	FY 2004
Met target	Met target	Met target
Maintain an average on-time delivery rate of 97% for stable isotopes and 95% for radioisotopes (95% overall).	Maintain an average on-time delivery rate of 97% for stable isotopes and 95% for radioisotopes.	Maintain an average on-time delivery rate of 97% for stable isotopes and 95% for radioisotopes.

Target 5: Ensure 98% of products/services provided to customers meet the terms (e.g., specific activity, enrichment, etc.) of the contract/sales order.

Commentary: The fiscal year 2007 target was met. Customer satisfaction with product specifications continues to be high. The Program ensured 99.8% of products and services met the terms of contract/sales orders. Customer responses include one complaint that the product received was not within the specifications required for its intended use. After

further analysis, a replacement shipment was made. An example of customer satisfaction includes appreciation for the extra effort taken to respond quickly in providing the needed sources requested which generated a positive impact on the critical supply for coal analyzers.

Future Plans: This target will continue to be tracked in fiscal year 2008 to ensure 98% of products/services provided to customers meet specifications. The Program will continue to ensure that 98% of products/services meet the terms of the contract/sales order. The Program will evaluate this target to determine if revisions will be required for the proposed transfer to the Office of Science in fiscal year 2009.

Documentation: Cumulative Business Results to Date report corroborated by monthly teleconferences with ORNL, LANL and BNL.

Related Prior Year Target 5 Performance:

FY 2006	FY 2005	FY 2004
Met target	Met target	Met target
Ensure 98% of products/services provided to customers meet the terms (e.g., specific activity, enrichment, etc.) of the contract/sales order.	Ensure 98% of products/services provided to customers meet the terms (e.g., specific activity, enrichment, etc.) of the contract/sales order.	Ensure 98% of products/services provided to customers meet the terms (e.g., specific activity, enrichment, etc.) of the contract/sales order.

Target 6: Meet facility availability schedules within 10% variance.

Commentary: Facility availability, as defined above, is when facilities are or could be operating, producing and distributing isotope products or services. The fiscal year 2007 target was met. Facility availability schedules were on track and included Program facilities and equipment, including shipping containers. This target was developed in FY 2006 to track progress made toward meeting the Department's strategic theme and program goals.

Future Plans: This target will continue to be tracked in fiscal year 2008 to meet facility availability schedules with 10% variance. The Program will continue to work with the Department's organizations that manage the facilities in an effort to increase the availability of facilities for isotope production. The Program will evaluate this target to determine if revisions will be required for the proposed transfer to the Office of Science in fiscal year 2009.

Documentation: Cost, Schedule and Performance Reports corroborated by monthly teleconferences with ORNL, LANL and BNL.

Related Prior Year Target 6 Performance:

FY 2006	FY 2005	FY 2004
Met target	N/A	N/A
Meet facility availability schedules within 10% variance.	Target developed in FY 2006; no prior year data.	Target developed in FY 2006; no prior year data.

Target 7: Maintain an average of 90% completion for all research isotope orders against scheduled production for the fiscal year.

Commentary: The fiscal year 2007 target was met. The Program maintained 100% completion for all research isotope orders, which is an improvement over the previous fiscal year. The Program's fiscal year 2006 was not met (89% completion) due to down time of the ORNL reactor, which resulted in a decrease in sufficient supply to fulfill requests for tungsten-188. To augment the Department's supply, tungsten-188 was ordered from Russia. This target was developed in fiscal year 2006 as a result of the Inspector General's (IG) Report IG-0709, "Management of the Department's Isotope Program," finding to establish a quantifiable performance measure for isotope production to more adequately serve the needs of the research community.

Future Plans: This target will continue to be tracked in fiscal year 2008 to meet all contractual requirements. The Program continues to import irradiated targets from foreign suppliers to enhance supply and meet increases in isotope demand. The Program will evaluate this target to determine if revisions will be required for the proposed transfer to the Office of Science in fiscal year 2009.

Documentation: Cumulative Business Results to Date report corroborated by monthly teleconferences with ORNL, LANL and BNL.

Related Prior Year Target 7 Performance:

FY 2006	FY 2005	FY 2004
Target not met	N/A	N/A
Maintain an average of 90% completion for all research isotope orders against scheduled production for the fiscal year.	Target developed in FY 2006; no prior year data.	Target developed in FY 2006; no prior year data.

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Independent Auditors' Report

September 30, 2007



KPMG LLP
2001 M Street, NW
Washington, DC 20036-3389

Independent Auditors' Report

The Isotope Program and
The Inspector General, United States Department of Energy:

We have audited the accompanying balance sheet of the United States (U.S.) Department of Energy's (Department) Isotope Program (the Program) (a component of the Department) as of September 30, 2007, and the related statements of net cost and changes in net position, and combined statement of budgetary resources for the year ended September 30, 2007 (hereinafter referred to as "financial statements"). The objective of our audit was to express an opinion on the fair presentation of these financial statements. In connection with our fiscal year 2007 audit, we also considered the Program's internal controls over financial reporting and performance measures and tested the Program's compliance with certain provisions of applicable laws, regulations, contracts, and grant agreements that could have a direct and material effect on these financial statements.

SUMMARY

As stated in our opinion on the financial statements, we concluded that the Program's financial statements as of and for the year ended September 30, 2007, are presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles.

As discussed in our opinion on the financial statements, the Program changed its method of reporting the reconciliation of budgetary resources obligated to the net cost of operations in fiscal year 2007.

Our consideration of internal control over financial reporting resulted in the following conditions being identified as significant deficiencies:

- A. Controls over Accounting for Inventory at Brookhaven National Laboratory;
- B. Improvements Needed in Financial Reporting;
- C. Unclassified Network and Information Systems Security;
- D. Accounting for Property, Plant, and Equipment; and
- E. Accounting for Accounts Receivable at Oak Ridge National Laboratory.

We consider significant deficiencies A and B above to be material weaknesses.

We noted no deficiencies involving the design of the internal control over the existence and completeness assertions related to key performance measures.



Independent Auditors' Report, continued

The results of our tests of compliance with certain provisions of laws, regulations, contracts, and grant agreements disclosed no instances of noncompliance or other matters that are required to be reported herein under *Government Auditing Standards*, issued by the Comptroller General of the United States, and Office of Management and Budget (OMB) Bulletin Number (No.) 07-04, *Audit Requirements for Federal Financial Statements*.

The following sections discuss our opinion on the Program's fiscal year 2007 financial statements; our consideration of the Program's internal controls over financial reporting and performance measures; our tests of the Program's compliance with certain provisions of applicable laws, regulations, contracts, and grant agreements; and management's and our responsibilities.

OPINION ON THE FINANCIAL STATEMENTS

We have audited the accompanying balance sheet of the United States Department of Energy's Isotope Program as of September 30, 2007, and the related statements of net cost and changes in net position, and the combined statement of budgetary resources for the year ended September 30, 2007.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the United States Department of Energy's Isotope Program as of September 30, 2007, and its net costs, changes in net position, and budgetary resources for the year ended September 30, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 9 to the financial statements, the Program changed its method of reporting the reconciliation of budgetary resources obligated to the net cost of operations in fiscal year 2007.

The information in the Management's Discussion and Analysis and Required Supplementary Stewardship Information is not a required part of the financial statements, but is supplementary information required by U.S. generally accepted accounting principles and OMB Circular No. A-136, *Financial Reporting Requirements*. We have applied certain limited procedures, which consisted principally of inquiries of management regarding the methods of measurement and presentation of this information. However, we did not audit this information and, accordingly, we express no opinion on it.

The information in the Performance Results section and the Other Information section is presented for purposes of additional analysis and is not required as part of the financial statements. This information has not been subjected to auditing procedures and, accordingly, we express no opinion on it.



Independent Auditors' Report, continued

INTERNAL CONTROL OVER FINANCIAL REPORTING

Our consideration of the internal control over financial reporting was for the limited purpose described in the Responsibilities section of this report and would not necessarily identify all deficiencies in the internal control over financial reporting that might be significant deficiencies or material weaknesses.

A control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A significant deficiency is a control deficiency, or combination of control deficiencies, that adversely affects the Program's ability to initiate, authorize, record, process, or report financial data reliably in accordance with U.S. generally accepted accounting principles such that there is more than a remote likelihood that a misstatement of the Program's financial statements that is more than inconsequential will not be prevented or detected by the Program's internal control over financial reporting. A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the financial statements will not be prevented or detected by the Program's internal control.

In our fiscal year 2007 audit, we consider the deficiencies, described in Exhibits I and II, to be significant deficiencies in internal control over financial reporting. However, of the significant deficiencies described in Exhibits I and II, we believe that the significant deficiencies presented in Exhibit I are material weaknesses. Exhibit III presents the status of prior year reportable conditions.

INTERNAL CONTROL OVER PERFORMANCE MEASURES

Our tests of internal control over performance measures, as described in the Responsibilities section of this report, disclosed no deficiencies involving the design of the internal control over the existence and completeness assertions related to key performance measures.

COMPLIANCE AND OTHER MATTERS

The results of our tests of compliance described in the Responsibilities section of this report, exclusive of those referred to in the *Federal Financial Management Improvement Act of 1996* (FFMIA), disclosed no instances of noncompliance or other matters that are required to be reported herein under *Government Auditing Standards* or OMB Bulletin No. 07-04.

The results of our tests of FFMIA disclosed no instances in which the Program's financial management systems did not substantially comply with the three requirements discussed in the Responsibilities section of this report.

* * * * *



Independent Auditors' Report, continued

RESPONSIBILITIES

Management's Responsibilities. Management is responsible for the financial statements, including:

- Preparing the financial statements in conformity with U.S. generally accepted accounting principles;
- Preparing the Management's Discussion and Analysis (including the performance measures) and Required Supplementary Stewardship Information;
- Establishing and maintaining effective internal control; and
- Complying with laws, regulations, contracts, and grant agreements applicable to the Program, including FFMIA.

In fulfilling this responsibility, management is required to make estimates and judgments to assess the expected benefits and related costs of internal control policies.

Auditors' Responsibilities. Our responsibility is to express an opinion on the fiscal year 2007 financial statements of the Program based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and OMB Bulletin No. 07-04. Those standards and OMB Bulletin No. 07-04 require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Program's internal control over financial reporting. Accordingly, we express no such opinion.

An audit also includes:

- Examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements;
- Assessing the accounting principles used and significant estimates made by management; and
- Evaluating the overall financial statement presentation.

We believe that our audit provides a reasonable basis for our opinion.



Independent Auditors' Report, continued

In planning and performing our fiscal year 2007 audit, we considered the Program's internal control over financial reporting by obtaining an understanding of the Program's internal control, determining whether internal controls had been placed in operation, assessing control risk, and performing tests of controls as a basis for designing our auditing procedures for the purpose of expressing our opinion on the financial statements. We limited our internal control testing to those controls necessary to achieve the objectives described in *Government Auditing Standards* and OMB Bulletin No. 07-04. We did not test all internal controls relevant to operating objectives as broadly defined by the *Federal Managers' Financial Integrity Act of 1982*. The objective of our audit was not to express an opinion on the effectiveness of the Program's internal control over financial reporting. Accordingly, we do not express an opinion on the effectiveness of the Program's internal control over financial reporting.

As required by OMB Bulletin No. 07-04 in our fiscal year 2007 audit, with respect to internal control related to performance measures determined by management to be key and reported in the Management's Discussion and Analysis and Performance sections, we obtained an understanding of the design of internal controls relating to the existence and completeness assertions and determined whether these internal controls had been placed in operation. We limited our testing to those controls necessary to report deficiencies in the design of internal control over key performance measures in accordance with OMB Bulletin 07-04. However, our procedures were not designed to provide an opinion on internal control over reported performance measures and, accordingly, we do not provide an opinion thereon.

As part of obtaining reasonable assurance about whether the Program's fiscal year 2007 financial statements are free of material misstatement, we performed tests of the Program's compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the determination of the financial statement amounts, and certain provisions of other laws and regulations specified in OMB Bulletin No. 07-04, including certain provisions referred to in FFMIA. We limited our tests of compliance to the provisions described in the preceding sentence, and we did not test compliance with all laws, regulations, contracts, and grant agreements applicable to the Program. However, providing an opinion on compliance with laws, regulations, contracts, and grant agreements was not an objective of our audit and, accordingly, we do not express such an opinion.

Under OMB Bulletin No. 07-04 and FFMIA, we are required to report whether the Program's financial management systems substantially comply with (1) Federal financial management systems requirements, (2) applicable Federal accounting standards, and (3) the United States Government Standard General Ledger at the transaction level. To meet this requirement, we performed tests of compliance with FFMIA Section 803(a) requirements.

The Program's responses to the findings identified in our audit are presented in Exhibits I and II. We did not audit the Program's responses and, accordingly, we express no opinion on them.



Independent Auditors' Report, continued

This report is intended solely for the information and use of the Program's management, the Department of Energy's Office of Inspector General, OMB, the U.S. Government Accountability Office, and the U.S. Congress and is not intended to be and should not be used by anyone other than these specified parties.

KPMG LLP

March 31, 2011

Independent Auditors' Report
Exhibit I – Material Weaknesses

A. Controls over Accounting for Inventory at Brookhaven National Laboratory

During our fiscal year (FY) 2007 audit, we identified deficiencies in the United States Department of Energy's (Department) Isotope Program's (the Program) internal controls over Brookhaven National Laboratory's (Brookhaven) recording of inventory transactions and balances. Our audit procedures at Brookhaven included testing of inventory transactions from October 1, 2006 through September 30, 2007. While attempting to perform this testwork over Brookhaven inventory activity, we noted the following issues:

The first issue involved our request from Brookhaven for numerous schedules to test the FY 2007 inventory activity (e.g., lower of cost or market, excess inventory quantity, and decay analysis). The schedules provided to support the FY 2007 excess inventory quantity and lower of cost or market calculations were incorrect, and included mathematical errors and inconsistencies from prior year schedules.

The second issue involved our attempt to obtain a listing of inventory activity that occurred at Brookhaven during FY 2007. The Brookhaven staff specialist initially provided a spreadsheet that summarized production costs by isotope and activity category. We then requested a detail breakdown to support the summarized listing. Despite numerous requests, Brookhaven did not provide detailed listings containing sufficient information for us to select our samples until approximately seven months after our initial request. In addition, differences existed between the schedules provided and the general ledger; the differences were eventually deemed insignificant.

Additionally, although the documentation provided for the FY 2007 items was deemed adequate, the initial documentation provided was not clear or well-organized and required significant follow-up with Brookhaven and additional requests for support.

We found that internal controls were not in place to ensure that schedules to support general ledger balances were readily available and properly reconciled to the general ledger or to ensure that Brookhaven maintained adequate, sufficient supporting documentation for all accounting transactions.

As a result of the issues at Brookhaven, we found that:

The inaccurate inventory information and schedules (e.g., lower of cost or market, excess inventory quantity, and decay analysis) caused significant audit delays and additional audit work during the course of the FY 2007 audit.

In addition, without adequate controls in place to ensure that accurate, detailed schedules supporting general ledger balances are readily available, and that that sufficient supporting documentation is maintained and can be provided timely, Brookhaven risks noncompliance with Office of Management and Budget (OMB) Circular Number (No.) A-123, *Management Accountability and Control*.

Independent Auditors' Report
Exhibit I – Material Weaknesses, continued

OMB Circular No. A-123, Section II, Establishing Management Controls, states that transactions should be promptly recorded, properly classified, and accounted for in order to prepare timely accounts and reliable financial and other reports. The documentation for transactions, management controls, and other significant events must be clear and readily available for examination.

Recommendations:

We recommend the Manager of the Brookhaven Site Office direct Brookhaven to:

1. Ensure that all Brookhaven staff specialists responsible for preparation of inventory schedules for the Program (e.g., lower of cost or market, excess inventory quantity, and decay analysis) are provided with adequate training on the inventory transactions and schedules.

In addition, we recommend the Manager of the Brookhaven Site Office direct Brookhaven to develop and implement internal controls to ensure that:

2. Management reviews the inventory schedules prepared by the Brookhaven staff specialist to ensure accuracy of the schedules before the related accounting transactions are recorded;
3. Adequate, detail schedules to support general ledger balances are readily available, and are reconciled on a regular basis to the general ledger; and
4. Brookhaven maintains adequate, sufficient supporting documentation that is readily available for all accounting transactions.

Management's Response:

Management concurs with the recommendation, specifically providing:

1. It will request Brookhaven Science Associates (BSA) to ensure that the staff specialists responsible for the preparation of inventory schedules for the Program receive adequate training.
2. It will request BSA to enhance its internal policies by developing and implementing controls to ensure that:
 - a. Management reviews inventory schedules, prepared by the staff specialist, to ensure accuracy before the related accounting transactions are recorded;
 - b. Adequate, detail schedules to support general ledger balances are reconciled on a regular basis to the general ledger; and,

Independent Auditors' Report
Exhibit I – Material Weaknesses, continued

- c. Brookhaven maintains adequate, sufficient supporting documentation that is readily available for all accounting transactions.

B. Improvements Needed in Financial Reporting

During the FY 2007 audit, we also identified deficiencies in the internal controls in the preparation of the Program's financial reporting package, including the financial statements, notes, and Management's Discussion and Analysis (MD&A), and the ability to provide adequate supporting documentation for manual journal entries in a timely manner. The identified deficiencies precluded the Program from initially ensuring the accuracy and proper presentation of the balances and information in its financial reporting package.

The Department's Office of Finance and Accounting is responsible for the preparation of financial statements and the related notes for the Program. Program personnel are responsible for the preparation of the MD&A, Performance Results section, and Other Information section.

The Office of Finance and Accounting provided several draft financial statements and notes that had significant errors and inconsistencies. Additionally, comments and questions on early versions of the financial statements and notes were not addressed promptly in later versions. The lack of controls for management review of the financial reporting package resulted in these significant errors and inconsistencies.

Also, during our testing of a sample of 24 FY 2007 manual journal entries recorded by the Program, the Department's Chief Financial Officer's (CFO) staff was unable to provide timely, adequate supporting documentation beyond current (not historically maintained) written explanations, screen prints, and certain pivot tables to support the validity and accuracy for 12 of the 24 manual journal entries selected in our statistical sample. The CFO's office eventually provided adequate supporting documentation for most of the remaining 12 manual journal entries; however, the support was provided several months after our cutoff date for accepting supporting documentation.

The following criteria were cited during our testwork:

- OMB Circular No. A-123, *Management's Responsibility for Internal Control*, Section II, parts C and E;
- The Government Accountability Office's *Standards for Internal Control in the Federal Government*; and
- OMB Memorandum *Revised Implementation Guidance for the Federal Financial Management Improvement Act of 1996 (FFMIA)*.

Independent Auditors' Report
Exhibit I – Material Weaknesses, continued

Recommendations:

We recommend that:

1. The Director of the Office of Finance and Accounting and Program management coordinate reviews for concurrence of the Program's financial reporting package prior to submitting drafts to the auditor; and
2. The Department's Office of the Chief Financial Officer establish, implement, and monitor policies and procedures to ensure that adequate documentation is maintained and readily available to support all manual journal entries posted to the Department's general ledger for the Program.

Management's Response:

Management concurs with the recommendations, specifically providing:

1. Procedures have been implemented for review of the draft financial statements and notes by both the program office and the Office of Finance and Accounting prior to submission to the auditors. Each version of the financial statements will also be reviewed to ensure that all auditor comments are addressed prior to their submission.
2. Procedures were established to monitor and ensure that adequate documentation is maintained and readily available. Entries made at Headquarters are to be documented, either through attachments to the actual Standard Accounting and Reporting System (STARS) entries or through the maintenance of hard copy documents by the person responsible for the manual journal entry. Field offices were instructed to maintain adequate documentation for any manual journal entries made at their sites. Wherever practical, manual journal entries are being reviewed and posted by an individual other than the person responsible for inputting the entry. A primary responsibility of an independent poster is to ensure adequate documentation is available to support each entry. Judgmental samples of Headquarters' manual journal entries are periodically reviewed to validate that supporting documentation is properly maintained for these entries.

Independent Auditors' Report
Exhibit II – Significant Deficiencies

C. Unclassified Network and Information Systems Security

We noted network vulnerabilities and weaknesses in access and other security controls in unclassified information systems owned and operated by the United States Department of Energy (Department) and used by the Isotope Program (Program).

The Department maintains a series of interconnected unclassified networks and information systems. Federal and Departmental directives require the establishment and maintenance of security over unclassified information systems, including financial management systems. Past audits indicated significant weaknesses in selected systems and devices attached to the computer networks at some Department sites. The Department has implemented corrective actions to improve network security at the sites we, and the Department's Office of Health, Safety and Security (HSS), reviewed in prior years. However, we and the HSS continued to identify network security weaknesses at sites reviewed in fiscal year (FY) 2007, and the frequency and severity of those weaknesses remained consistent with our prior year findings. The Department recognizes these weaknesses and has categorized unclassified cyber security as a significant issue in its *Federal Managers' Financial Integrity Act* assurance statement for FY 2007. Significant improvements are still needed in the areas of password management, configuration management, and restriction of network services.

Our FY 2007 audit also disclosed weaknesses in access at several sites, similar to our prior year findings. Specifically, we noted weaknesses in the review and approval of user access privileges, password security, monitoring of networks for questionable activity, and usage of versions of applications and operating system software that were outdated or not appropriately patched. We also noted weaknesses in the cyber security programs at certain locations in which Federal cyber security requirements and Departmental policies and controls were not properly implemented. Further, the Department's Office of Inspector General also reported deficiencies in the Department's network and information system risk management, configuration management, and access controls in its evaluation report on *The Department's Unclassified Cyber Security Program*, dated September 2007. Matters discussed in that report included an examination of non-financial systems.

The Department has acknowledged the need to improve its information systems security and other information technology controls. In FY 2007, the Department's Chief Information Officer (CIO) continued to implement a comprehensive revitalization plan designed to improve the management of its information security program, and issued enhanced cyber security guidance to strengthen controls and reduce network vulnerabilities. The Cyber Security Revitalization Plan, launched in FY 2006, is a collaborative effort between the Office of the CIO (OCIO), the Under Secretaries and other senior management to identify and resolve cyber security problems, provide site assistance, and follow-up on corrective actions. Once fully implemented, these initiatives and new policies and procedures should strengthen the Department's overall cyber security program.

Independent Auditors' Report
Exhibit II – Significant Deficiencies, continued

The identified weaknesses in network vulnerabilities and access controls increase the risk that malicious destruction or alteration of data or unauthorized processing could occur. Because of our concerns, we performed supplemental procedures and identified compensating controls that mitigate the potential effect of these security weaknesses on the integrity of the Department's financial systems.

Recommendation:

Because the Program does not have the ability to affect changes on the Department's network security, no further action is needed by the Program other than to monitor the progress of the OCIO. While considerable progress has been achieved by the Department, continued focus is needed to resolve the network vulnerability and access control weaknesses described above. Therefore, we recommended in the Department's Independent Auditors' Report dated November 9, 2007 that the Department's program officials, in conjunction with the CIO, fully implement policies and procedures to ensure that the Federal information security standards are met and that the Department's networks and information systems are adequately protected against unauthorized access.

Detailed recommendations to address the issues discussed above have been separately reported to the Department's program offices and the OCIO.

Management's Response:

Management concurs with the recommendation as presented, with the recognition that the Department's OCIO is the lead office in affecting change on the Department's information systems.

D. Accounting for Property, Plant, and Equipment

During the FY 2007 audit, we noted deficiencies in the Program's internal controls in accounting for property, plant, and equipment (PP&E) at Sandia National Laboratory (Sandia) and Los Alamos National Laboratory (LANL), specifically related to accounting for depreciation expense and inter-entity transfers.

Depreciation Expense

While recalculating the Program's FY 2007 depreciation at LANL, we noted that the depreciation expense recorded for the System Beam Ion was overstated. Specifically, the depreciation recorded by LANL for FY 2007 was approximately \$597,000, while our recalculation showed a yearly depreciation expense of approximately \$359,000, resulting in an overstatement of approximately \$238,000 in expense and accumulated depreciation. We posted a proposed adjustment to the Summary of Audit Differences, which was attached to the FY 2007 management representation letter.

Independent Auditors' Report
Exhibit II – Significant Deficiencies, continued

LANL was not recording depreciation for the System Beam Ion using the correct service life according to the Department's *Accounting Handbook*. The System Beam Ion falls under the 10-year life category.

The Department's *Accounting Handbook*, Chapter 10, paragraph 7d(1), states, "The list in Attachment 10-1 shall be used to determine depreciation rates for all items of completed Plant and Capital Equipment (P&CE) except for those items having service lives that are materially different from normal averages because of the peculiarity of their use or other special conditions."

Inter-entity Transfers

Additionally, while testing the Program's FY 2007 equipment roll-forward from Sandia, we noted that one of the assets in completed PP&E, an Annular Core Research Reactor (ACRR) Storage Pool Liner, had no accumulated depreciation and/or current year depreciation expense. Upon further inquiry, we discovered that the ACRR Storage Pool Liner had been transferred via a Transfer of Facilities and Rescission of Management Agreement (MOU) from the Program (Office of Nuclear Energy (NE)) to the Department's Defense Program (National Nuclear Security Administration (NNSA)) in September 2006, but no adjustment was recorded related to the transfer.

When originally received, the ACRR Storage Pool Liner was mistakenly assigned two property numbers because it was purchased with funding from two funding sources (TC and VE). (Fund code VE is for the Program, and fund code TC is for NNSA.) However, existing internal controls detected the error (duplicate numbers for the same asset). The resulting correction reversed the VE portion out of Sandia's system and added it to the TC portion. The entire asset (\$637,906) was then capitalized and depreciated under TC.

A manual entry was also recorded in STARS allocating the asset value to the two fund types. As a result, a portion of the asset was recorded under VE in STARS, and the entire accumulated depreciation balance (and depreciation expense) was recorded under TC as it flowed from the Fixed Asset module to STARS.

The errors relating to the partial allocation of the asset to different fund types resulted from an inexperienced Fixed Asset Team Lead. The Team Lead has since been replaced with a higher-level staff member.

In addition, existing internal controls were not operating sufficiently to ensure proper communication between programmatic and accounting personnel within Sandia to record the transfer of ownership between Department programs on Sandia's books.

Finally, the MOU between NE and NNSA was signed in September 2006. However, because programmatic line staff were not aware of the accounting implications of this MOU, it was not forwarded to the Accounting Department until May 20, 2008. Until that time, accounting personnel did not know of the ownership change.

Independent Auditors' Report
Exhibit II – Significant Deficiencies, continued

By not recording depreciation expense for the ACRR Storage Pool Liner in the correct fund code prior to the asset's transfer, the Program's accumulated depreciation, depreciation expense, and net position account balances were misstated. In addition, by not recording the transfer of the ACRR Storage Pool Liner to the Department's Defense Program, the Program initially overstated its completed PP&E and net position by \$151,921. This error was subsequently corrected by the Program in the final FY 2007 financial statements.

The following criteria were cited during our testwork:

The Department's *Accounting Handbook*, Chapter 10, Plant and Capital Equipment (P&CE), states "Depreciation shall be recorded monthly." Chapter 10 further states, "Depreciation on the P&CE in each use status shall be treated as follows: (1) In Service. Depreciation on P&CE in service shall be charged to the appropriate budget and reporting classification (for example, production cost, development, research, or program directions) in which the items are used."

Per the Department's *Accounting Handbook* Chapter 12, Inter-Entity Transfers, "...Capital Equipment shall be transferred based on the acquisition cost less accumulated depreciation. Completed Plant and Capital Equipment shall be credited for the acquisition cost, Accumulated Depreciated debited for the amount of depreciation accumulated, and Financing Sources Transferred Out debited for the net book value."

Recommendations:

Depreciation Expense

We recommend that NNSA's Field Chief Financial Officer, in conjunction with the Manager, Los Alamos Site Office, direct LANL to correct the monthly depreciation expense charged for the System Beam Ion to be consistent with Department of Energy accounting requirements (i.e., the Department's *Accounting Handbook*) and to correct its useful life for future depreciation expense calculations.

Inter-entity Transfers

Additionally, we recommend that NNSA's Field Chief Financial Officer, in conjunction with the Manager, Sandia National Laboratory, direct Sandia to:

1. Record an entry to move the portion of the asset in fund code VE to fund code TC in STARS to comply with the MOU; and
2. Develop and implement internal control procedures to strengthen communication between programmatic and accounting personnel.

Independent Auditors' Report
Exhibit II – Significant Deficiencies, continued

Management's Response:

Management concurs with the recommendations, specifically providing:

The System Ion Beam at LANL is being depreciated in Sunflower over a 10-year period. The useful life was changed on February 22, 2006, from 15 to 10. The acquisition date issue is what is causing a problem with the depreciation. The acquisition date was changed on it, and the depreciation entry did not account for the adjustment due to Sunflower system limitations. Sunflower does catch-up depreciation if the useful life is changed, however it doesn't adjust depreciation if the acquisition date is changed, which is what happened in this case. The corrective action plan that has requested Sunflower to make this programming fix was implemented in fiscal year 2009.

Sandia will:

- Record an entry to move the portion of the asset in Fund Code VE to Fund Code TC in order to comply with the MOU; and,
- Improve communication and procedures between programmatic and accounting personnel.

E. Accounting for Accounts Receivable at Oak Ridge National Laboratory

While performing sales cut-off testwork over the last five inventory shipments of FY 2007 and the first ten shipments of FY 2008 at Oak Ridge National Laboratory (ORNL), we noted five customer orders with a total dollar value of approximately \$347,000 that were shipped in September 2007 (FY 2007), but were incorrectly recorded as October 2007 sales and FY 2008 revenue.

Additionally, while performing testwork over accounts receivable balances as of September 30, 2007, we noted seven customers that had both an accounts receivable balance (debit) and an advance balance (credit) at September 30, 2007 for the same product provided to the customer. The advance payment balances should have been applied to satisfy the outstanding receivable balances, thereby eliminating both balances from the fiscal year-end financial statements. These balances totaled \$184,000.

The program offices were delayed in providing supporting shipping documentation and notification that these sales had occurred in FY 2007 to the Isotope Business Office (IBO); the IBO did not receive this information until early FY 2008. In addition, ORNL did not have procedures in place to ensure that revenues and expenses occurring between the end of ORNL's business calendar year and the actual close of the Department's fiscal year-end were properly accrued. Due to these issues, the IBO did not properly account for these sales in FY 2007.

Because of system upgrades to ORNL's Systems, Applications, and Products in Data Processing (SAP) system that occurred during FY 2007, certain customer payments, and

Independent Auditors' Report
Exhibit II – Significant Deficiencies, continued

shipments were not properly applied to the appropriate accounts receivable and advances subsidiary ledgers. ORNL did not have manual controls in place to compensate for this system issue.

Improper sales cut-off could lead to inaccuracies in the Program's accounts receivable, inventory, customer advances, sales revenue, and operating expense (i.e., cost of goods sold) account balances.

By recording sales in the incorrect fiscal year, the Program initially understated sales and accounts receivable, and overstated inventory and customer advances as of September 30, 2007. This error was subsequently corrected by the Program in the final FY 2007 financial statements.

Improper accounting of cash receipts and customer shipments could lead to inaccuracies in the Program's accounts receivable and customer advances account balances. At September 30, 2007, the Program initially overstated both accounts receivable and customer advances by approximately \$184,000. This error was subsequently corrected by the Program in the final FY 2007 financial statements.

Statement of Federal Financial Accounting Standard (SFFAS) No. 7, *Accounting for Revenue and Other Financing Sources and Concepts for Reconciling Budgetary and Financial Accounting*, states that "Exchange revenues arise when a Government entity provides goods and services to the public or to another Government entity for a price...These accounting standards recognize exchange revenue at the time that a Government entity provides goods or services to the public or to another Government entity...Only revenue classified as exchange revenue should be matched with costs."

SFFAS No. 1, *Accounting for Selected Assets and Liabilities*, states that "A receivable should be recognized when a federal entity establishes a claim to cash or other assets against other entities, either based on legal provisions, such as a payment due date...or goods or services provided...Federal entities may receive advances and prepayments from other entities for goods to be delivered or services to be performed...After the revenue is earned (goods or services are delivered, or performance progress is made according to engineering evaluations), the entity should record the appropriate amount as a revenue or financing source and should reduce the liability accordingly."

Recommendations:

We recommend that the Director, Isotope Program at Headquarters, issue guidance requiring that prior to the final fiscal year closing process, the ORNL IBO contact all sites within the Program regarding planned shipments before fiscal year end. All program contractors are required to respond with proper and timely information to the ORNL IBO regarding these shipments. Based on the information provided, the ORNL IBO will be responsible for recording or accruing entries to properly report the revenue for these shipments. Contractors at each individual program site will be responsible for properly recording or accruing entries to properly report the cost of these sales.

Independent Auditors' Report
Exhibit II – Significant Deficiencies, continued

Additionally, we recommend that the Manager, Oak Ridge Office, require the IBO, through the management and operating contractor at ORNL, to:

1. Develop and implement review procedures to ensure that duplicate balances are not reported for the same invoice/payment in both accounts receivable and customer advance balances.
2. Correct the noted system issue to ensure appropriate accounting for receipts and shipment transactions.

Management's Response:

Management concurred with the recommendations, noting specifically:

- 1 The Isotope Program will include in its annual program and financial guidance and memorandum direction to the Isotope Business Office, ORNL, to contact all sites within the Program prior to the fiscal year closing process regarding shipments planned before the end of the fiscal year so that accruals can be made to appropriate account balances. In addition, the Program will include in the annual guidance memorandum direction to each isotope producing and processing site to respond with proper and timely shipping information to Isotope Business Office, ORNL.
- 2 DOE directed ORNL to implement system modifications to ensure that appropriate accounting for receipts and shipment transactions occur. ORNL provided a corrective action plan by July 31, 2008 that was implemented during fiscal year 2009, that ensures duplicate balances are not reported for the same invoice/payment in both accounts receivable and customer advance balances.



Independent Auditors' Report
Exhibit III – Status of Prior Year Reportable Conditions

Prior Year Reportable Condition

Status at September 30, 2007

**(with parenthetical disclosure
of year first reported)**

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Accounting Treatment of Property, Plant, and Equipment at Los Alamos National Laboratory – considered a Material Weakness (2006) | Matter considered closed |
| 2. Improvements Needed in Financial Reporting – considered a Material Weakness (2006) | Not fully implemented – financial reporting issues continue to be reported as a Material Weakness in Exhibit I |
| 3. Controls over Accounting for Inventory at Brookhaven National Laboratory – considered a Material Weakness (2006) | Not fully implemented – Brookhaven National Laboratory inventory accounting issues continue to be reported as a Material Weakness in Exhibit I |
| 4. Unclassified Information Systems Security – considered a Reportable Condition (1999) | Not fully implemented – unclassified network and information systems security issues continue to be reported as a Significant Deficiency in Exhibit II |

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

[Financial Statements](#)

September 30, 2007

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Balance Sheet

As of September 30, 2007

(in dollars)

Assets:	<u>2007</u>
Intragovernmental:	
Fund balance with Treasury (note 2)	\$ 25,208,542
Accounts receivable (note 3)	<u>95,763</u>
Total intragovernmental assets	25,304,305
Accounts receivable, net (note 3)	426,973
Inventories held for sale, net (note 4):	
Radioactive isotopes	1,919,681
Stable isotopes	3,592,818
Allowance - isotope inventories	<u>(4,080,581)</u>
Total inventories held for sale, net	1,431,918
Equipment, net (note 5)	<u>18,216,221</u>
Total assets	<u><u>\$ 45,379,417</u></u>
 Liabilities:	
Intragovernmental liabilities covered by budgetary resources:	
Customer advances	\$ 33,055
Non-Intragovernmental liabilities covered by budgetary resources:	
Accounts payable/accrued expenses	7,892
Customer advances	<u>1,125,288</u>
Total liabilities	1,166,235
Commitments and contingencies (notes 6 and 7)	
Net Position:	
Cumulative results of operations - earmarked funds	<u>44,213,182</u>
Total liabilities and net position	<u><u>\$ 45,379,417</u></u>

The accompanying notes are an integral part of these statements.

UNITED STATES DEPARTMENT OF ENERGY

ISOTOPE PROGRAM

Statement of Net Cost

For the year ended September 30, 2007

(in dollars)

<u>2007</u>	<u>Isotope Production and Distribution</u>		<u>Infrastructure maintenance and enhancements</u>	<u>Total</u>
	<u>Radioactive Isotopes</u>	<u>Stable Isotopes</u>		
Functional classification:				
Energy, program costs:				
Intragovernmental	\$ (153,466)	—	(4,000)	(157,466)
Public	(13,510,919)	(459,390)	(15,016,587)	(28,986,896)
	<u>(13,664,385)</u>	<u>(459,390)</u>	<u>(15,020,587)</u>	<u>(29,144,362)</u>
Exchange revenues:				
Intragovernmental	435,964	118,208	—	554,172
Public	11,640,794	3,874,626	—	15,515,420
	<u>12,076,758</u>	<u>3,992,834</u>	<u>—</u>	<u>16,069,592</u>
Net cost of operations	\$ <u><u>(1,587,627)</u></u>	<u><u>3,533,444</u></u>	<u><u>(15,020,587)</u></u>	<u><u>(13,074,770)</u></u>

The accompanying notes are an integral part of these statements.

UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM

Statement of Changes in Net Position
For the year ended September 30, 2007
(in dollars)

	<u>2007</u>
Beginning balance, cumulative results of operations	\$ <u>40,442,458</u>
Budgetary financing sources -	
Funding from the Radiological Facilities Management Unit	15,634,000
Other financing sources:	
Transfers-in without reimbursement	209,837
Imputed financing from costs absorbed by others	<u>1,001,657</u>
Total financing sources	<u>16,845,494</u>
Net cost of operations	(13,074,770)
Net change	<u>3,770,724</u>
Ending balance, cumulative results of operations	\$ <u><u>44,213,182</u></u>

The accompanying notes are an integral part of these statements.

UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM
Statement of Budgetary Resources
For the year ended September 30, 2007
(in dollars)

	<u>2007</u>
Budgetary Resources:	
Unobligated balance, brought forward, October 1	\$ 11,784,876
Budget authority	
Spending authority from offsetting collections	
Earned	
Collected	33,797,590
Change in receivables from Federal sources	67,403
Change in unfilled customer orders	
Advance received	<u>(1,280,613)</u>
Subtotal	<u>32,584,380</u>
Total Budgetary Resources	<u><u>\$ 44,369,256</u></u>
Status of Budgetary Resources:	
Obligations incurred: reimbursable	\$ 31,418,165
Unobligated balance: apportioned available	9,792,209
Unobligated balance not available	<u>3,158,882</u>
Total status of budgetary resources	<u><u>\$ 44,369,256</u></u>
Change in Obligated Balance:	
Obligated balance, net	
Unpaid obligations, brought forward, October 1	\$ 8,818,974
Uncollected customer payments from Federal sources	
brought forward, October 1	<u>(28,360)</u>
Total unpaid obligated balance, net	8,790,614
Obligations incurred, net	31,418,165
Less: Gross outlays	(27,883,925)
Change in uncollected customer payments from Federal sources	<u>(67,403)</u>
Obligated balance, net, end of period	
Unpaid obligations	12,353,214
Uncollected customer payments from Federal sources	<u>(95,763)</u>
Total, unpaid obligated balance, net, end of period	<u><u>\$ 12,257,451</u></u>
Net Outlays:	
Net Outlays:	
Gross outlays	\$ 27,883,925
Offsetting collections	<u>(32,516,977)</u>
Net Outlays	<u><u>\$ (4,633,052)</u></u>

The accompanying notes are an integral part of these statements.

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Notes to the Financial Statements

September 30, 2007

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Notes to the Financial Statements

September 30, 2007

1) Description of Reporting Entity, Basis of Presentation and Accounting, and Summary of Significant Accounting Policies

(a) Reporting Entity

The United States (U.S.) Department of Energy's (the Department) Isotope Program's (the Program) mission is to maintain the infrastructure required to support the national need for a reliable supply of isotope products, services, and related technology used in medicine, industry, and research. This assures that critical isotope production infrastructure is operated in a safe, secure, environmentally-compliant and cost-effective manner, and is available to users who need Department-produced isotopes. The Program is a user of Departmental facilities and provides funding through the Department's field offices to management and operating (M&O) contractors for the production and distribution of isotopes and related services. Since the Program uses only a small portion of the capacity of each facility, management of the facilities producing isotopes and related services is the responsibility of other programs within the Department. The Program provides program direction and oversight for the production and sale of its products and services. Except as indicated in note 7, the full cost of the products and services utilized by the Program at Departmental facilities, including such items as labor, benefits and packaging, is reflected in the Statement of Net Cost.

Isotope production and research and development activities are performed at the following sites: Brookhaven National Laboratory (BNL), Upton, New York; Los Alamos National Laboratory (LANL), Los Alamos, New Mexico; Oak Ridge National Laboratory (ORNL), Oak Ridge, Tennessee; Idaho National Laboratory (INL), Idaho Falls, Idaho; and Sandia National Laboratories (Sandia), Albuquerque, New Mexico. Strontium-90 is stored at Pacific Northwest National Laboratory (PNNL), Richland, Washington. The Program also funds the operation of the helium-3 processing facility, Building 236H, at Savannah River Site (SRS), Aiken, South Carolina.

The Program's activities are separated into the following segments:

Isotope Production and Distribution

Isotopes are atoms of an element that have the same atomic number, but different atomic masses. Isotopes may either be stable or radioactive.

Stable Isotopes – Stable isotopes include those that do not decay or emit radiation, as well as naturally occurring radioactive isotopes (radioisotopes) that have very long half-lives and hence low radioactivity. Isotopes classified as stable isotopes in the accompanying financial statements include those previously produced in calutrons and by other means, and are contained in inventory at ORNL. The Program is not currently producing new stable isotopes.

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Notes to the Financial Statements

September 30, 2007

Radioisotopes – Radioisotopes can be produced in reactors or accelerators. Isotopes classified as reactor-produced are radioisotopes produced through neutron capture or fission followed by radioactive decay. Some radioisotopes are extracted from the waste byproducts of the Department's weapons program activities. Isotopes classified as accelerator-produced are radioisotopes produced by bombarding materials with charged atomic particles followed by radioactive decay.

Infrastructure Maintenance and Enhancement

The Program maintains facilities in a safe and environmentally-compliant condition for the continued production, packaging, and shipment of isotopes and other services needed in medical diagnostic and therapeutic applications and other scientific research used by Federal and non-Federal entities. Infrastructure maintenance includes facility and shipping container maintenance, radiological monitoring, and facility inspections. Infrastructure enhancement includes investments in processing techniques, including safety enhancements, for existing radioisotopes as well as further development of production techniques for radioisotopes that are of interest to the isotope-user community.

(b) Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles to report only the Program's financial position, net costs, changes in net position, and budgetary resources, and not those of the Department taken as a whole.

The Department's headquarters, field offices, and the M&O contractors operating the facilities discussed in note 1(a) record Program activity in their accounting systems. The M&O contractors integrate their accounting systems with the Department through the use of reciprocal accounts. All M&O contractors are required under provisions of their respective contracts to maintain a separate set of accounts and records for recording and reporting Program financial transactions in accordance with Departmental accounting practices and procedures. The accompanying financial statements are prepared by extracting and reclassifying Program-related data from the financial records of the Department and its M&O contractors.

Program expenses are summarized in the statement of net cost by strategic goal, which represents the major elements of the Department's mission. All Program activities are classified in one strategic theme, Energy Security. The Energy Security theme is supported by the following strategic goal: Reduce greenhouse gas emissions and other environmental impacts (water use, land use, criteria pollutants) from our energy production and use. The Program contributes to this goal.

Intragovernmental activities result from activity with other Federal agencies. All other accounts result from activity with parties outside the Federal government.

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Notes to the Financial Statements

September 30, 2007

(c) *Basis of Accounting*

The Program's financial statements are prepared using the accrual method of accounting. The accrual method of accounting requires recognition of the financial effects of transactions, events, and circumstances in the periods when those transactions, events, and circumstances occur, regardless of when cash is received or paid. The Program also uses budgetary accounting to facilitate compliance with legal constraints and to keep track of its budget authority at the various stages of execution, including allotment, obligation, and eventual outlay.

(d) *Fund Balance with Treasury*

Program cash receipts and disbursements are processed through the U.S. Department of the Treasury (the Treasury). Funds with the Treasury are available to the Program through use of a revolving fund to pay current liabilities and to finance authorized purchase commitments.

(e) *Accounts Receivable*

Accounts receivable are reduced to net realizable value by an allowance for uncollectible accounts. This allowance has been determined based on an analysis of outstanding balances, past experience, and present market conditions.

(f) *Inventories Held for Sale*

Program inventories include stable isotopes, reactor-produced isotopes, and accelerator-produced isotopes with half-lives in excess of 75 days. However, any isotope with a 75-day half-life or less and carrying a value greater than \$35,000 is written back into inventory at fiscal year end. Periodic entries are recorded to reflect any decay losses. All inventories are valued based on average cost, reduced for quantities on hand in excess of sales over the previous five years, and are stated at the lower of cost or market value.

(g) *Equipment*

The Program is a user of Departmental production facilities and, as such, does not own or fully control the land, buildings and other assets it uses, but rather is charged by other programs for the use of those assets.

The Program makes equipment purchases as needed for Program operations, such as remote handling devices and shipping containers. Equipment costing more than \$50,000 with an expected useful life of two or more years is capitalized and depreciated on a straight-line basis over the estimated useful life of the asset, ranging from 5 to 50 years.

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Notes to the Financial Statements

September 30, 2007

(h) Liabilities

The Program's accounts payable and accrued expenses represent amounts of monies or other resources likely to be paid as a result of a transaction or event that has already occurred. See Note 1(k) for discussion of customer advances.

(i) Annual, Sick, and Other Leave

The Office of Nuclear Energy (NE) provides for the Program's annual, sick, and other leave. The net cost of operations includes annual, sick, and other leave costs attributable to the Program for the year ended September 30, 2007, and an equivalent amount is included as imputed financing, as an other financing source.

Annual leave is expensed as it is earned. Sick and other leave are expensed as taken.

(j) Revolving Fund Structure

The Fiscal Year 1990 *Energy and Water Appropriations Act*, Public Law 101-101 (1990 Act), established a revolving fund to be used to carry out the Program's production, distribution, and sale of isotopes and related services. The 1990 Act required that isotope fees be set to provide full cost recovery. However, Public Law 103-316 modified predecessor acts to allow prices charged for the Program's products and services to be based on production costs, market value, U.S. research needs, and other factors. See Note 1(m) for additional discussion of Public Law 103-316.

(k) Exchange Revenues and Pricing Policy

As a revolving fund, the Program receives all revenues from sales of isotopes and related services. Certain customers may be required to make payment in advance of delivery. These advances are recorded as customer advances. Exchange revenues are recognized when goods have been delivered or services performed.

The Program prices isotopes sold for medical and industrial applications on a full cost-recovery basis. Isotopes sold for research and development are priced to recover direct costs of production.

The Program sells products to various public customers such as colleges and universities, and research institutions, as well as to other Federal agencies. Higher prices for research and development isotopes based on full cost might reduce the quantity of isotopes demanded; therefore, the difference between revenue received and such higher prices does not necessarily provide an indication of revenue foregone.

**UNITED STATES DEPARTMENT OF ENERGY
ISOTOPE PROGRAM**

Notes to the Financial Statements

September 30, 2007

(l) *Concentration of Risk*

A substantial amount of the Program's revenue is derived from a small percentage of commercial customers (approximately 84% of the Program's combined revenues were provided by eight customers in fiscal year 2007). Commercial customers are charged a fee which is held for unanticipated abnormal events such as spills, defective products, or equipment failures. If the sale of commercial isotopes drastically decreases, additional funding may be required to maintain isotope staff at current levels. This is not considered to be a significant risk for the next fiscal year.

(m) *Budgetary Financing Sources*

The Fiscal Year 1995 *Energy and Water Appropriations Act*, Public Law 103-316, established annual funding for the Program in the Department's energy supply, research, and development appropriations. The Radiological Facilities Management Unit funds payments to the Program to maintain the infrastructure required to support the national need for a reliable supply of isotope products, services, and related technology used in medicine, industry and research. The Program recognizes these payments as a financing source when payments are received. The Program received approximately \$15.6 million in funding from the Radiological Facilities Management Unit during fiscal year 2007.

(n) *Pensions and Other Retirement Benefits*

All permanent Departmental employees participate in either the Civil Service Retirement System (CSRS) or the Federal Employees Retirement System (FERS). Both are contributory pension plans and are not covered under the Employee Retirement Income Security Act of 1974. Retirement benefit expense under CSRS is equivalent to 7.5% in fiscal year 2007 of eligible employee compensation and under FERS is variable based upon options chosen by the participant.

Actuarially determined data for CSRS and FERS regarding the present value of accumulated benefits, assets available for benefits, and unfunded pension liability, are maintained and reported by the Office of Personnel Management (OPM) and are not allocated to individual departments and agencies.

Statement of Federal Financial Accounting Standards (SFFAS) Number (No.) 5, *Accounting for Liabilities of the Federal Government*, requires federal entities to recognize expense for employees' retirement plan benefits equal to the service costs for these employees for the year based on the plans' actuarial cost methods and assumptions. The difference between the retirement benefits expense and contributions made by the entity is recorded as an imputed financing source, as these costs will ultimately be funded by OPM.

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September 30, 2007

(o) *Earmarked Funds*

SFFAS No. 27, *Identifying and Reporting Earmarked Funds*, requires separate identification of earmarked funds on the financial statements. Earmarked funds are financed by specifically identified revenues, which remain available over time. The Program's only fund is an earmarked fund. The fund includes receipts generated from the sales of isotopes and services that are used for isotope production and distribution, and infrastructure maintenance and enhancement activities performed by the Program. These specifically identified revenues are received primarily from sources external to the Federal Government, are required by statute to be used for designated activities, and must be accounted for separately from the Government's general revenue.

(p) *Use of Estimates*

The preparation of the financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(q) *Tax Status*

The Program, as a component of a Federal entity, is not subject to Federal, state, or local income taxes. Accordingly, no provision for income taxes is recorded in the accompanying financial statements.

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(2) Fund Balance with Treasury

Revolving fund balance consists of the following at September 30, 2007:

	<u>2007</u>
Unobligated budgetary resources:	
Available	\$ 9,792,209
Other unobligated balances not available	3,158,882
Obligations balance not yet disbursed:	
Undelivered orders	12,345,322
Receivables for reimbursements earned	(95,763)
Accounts payable and deposit fund liabilities	<u>7,892</u>
Total Fund Balance with Treasury	\$ <u><u>25,208,542</u></u>

(3) Accounts Receivable

Accounts receivable consists of the following at September 30, 2007:

	<u>2007</u>
Accounts receivable from the Public	\$ 426,973
Less allowance for uncollectible accounts	<u>-</u>
Total accounts receivable from the public, net	\$ <u><u>426,973</u></u>
Intragovernmental accounts receivable	\$ <u><u>95,763</u></u>

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(4) Inventories Held For Sale, Net

Inventories held for sale consist of the following at September 30, 2007:

	<u>2007</u>		
	<u>Radioisotopes</u>	<u>Stable Isotopes</u>	<u>Total</u>
Costs	\$ 1,919,681	3,592,818	5,512,499
Less:			
Allowance for excessive inventory quantities	(640,312)	(3,428,694)	(4,069,006)
Allowance for lower of cost or market value	<u>(11,575)</u>	<u>—</u>	<u>(11,575)</u>
Total inventories, net	<u>\$ 1,267,794</u>	<u>164,124</u>	<u>1,431,918</u>

(5) Equipment, Net

Equipment consists of the following at September 30, 2007:

	<u>2007</u>
Production equipment	\$ 23,229,878
Less accumulated depreciation	<u>(5,013,657)</u>
Total Equipment - Net	<u>\$ 18,216,221</u>

(6) Shutdown of Calutron Facility

The Program has placed the Calutron facility used in the electromagnetic separation of stable isotopes in Oak Ridge, Tennessee into a standby, but operable, condition until it is no longer needed or replacement machines are available.

The Program will continue to fund surveillance and maintenance (S&M) activities necessary for maintaining the facility in a standby mode. The cost of the S&M activities required to be performed prior to transfer of the facility to the Department's Environmental Management (EM) Office is estimated to be less than \$1.0 million per year. The Department is not currently proceeding with activities leading to the permanent deactivation of the facility and, accordingly, no provision for the

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cost of S&M or other standby activities related to the Calutron facility is included in the accompanying financial statements.

(7) Potential Decontamination and Decommissioning (D&D) Costs

The Program may be responsible for a portion of D&D for other facilities at which it conducts operations. As of September 30, 2007, the Department has not estimated D&D costs for such facilities, and the Program has not been assigned responsibility for D&D costs. Accordingly, no provision for D&D costs at other isotope facilities is included in the accompanying financial statements.

(8) Apportionment Categories of Obligations Incurred, Direct vs. Reimbursable

All Program obligations are considered Reimbursable and are Category B apportionments.

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(9) Reconciliation of Budgetary Resources Obligated to Net Cost of Operations

In accordance with revised OMB Circular No. A-136, *Financial Reporting Requirements*, dated June 29, 2007, the information previously included in the Statement of Financing is presented as a footnote disclosure and is no longer a basic financial statement as had been presented in prior years.

	<u>2007</u>
Resources used to finance activities:	
Budgetary resources obligated:	
Obligations incurred	\$ 31,418,165
Less spending authority from offsetting collections and recoveries	<u>(32,584,381)</u>
Net obligations	<u>(1,166,216)</u>
Other resources:	
Funding from the Radiological Facilities Management Unit	15,634,000
Imputed financing from costs absorbed by others	1,001,657
Transfers-in without reimbursement	<u>209,837</u>
Net other resources used to finance activities	<u>16,845,494</u>
Total resources used to finance activities	<u>15,679,278</u>
Resources used to finance items not part of net cost of operations:	
Change in budgetary resources obligated for goods, services, and benefits ordered but not yet provided	(3,855,097)
Resources that finance the acquisition of assets	(6,134,432)
Other resources and adjustments	<u>(820,143)</u>
Total resources used to finance items not part of net cost of operations	<u>(10,809,672)</u>
Total resources used to finance net cost of operations	<u>4,869,606</u>
Components of the net costs of operations that will not require or generate resources in the current period:	
Components requiring or generating resources in future periods:	
Increase in exchange revenue receivable from the Public	<u>434,504</u>
Components not requiring or generating resources:	
Depreciation and amortization	736,778
Revaluation of assets or liabilities	399,593
Cost of goods sold	6,691,236
Other	<u>(56,947)</u>
Total components of net cost of operations that will not require or generate resources	<u>7,770,660</u>
Total components of net cost of operations that will not require or generate resources in the current period	<u>8,205,164</u>
Net cost of operations	<u><u>\$ 13,074,770</u></u>

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(10) Statement of Budgetary Resources Disclosures

A. Restrictions on the Use of Unobligated Balances

Receipts from customers are reported as budget authority in the Statement of Budgetary Resources. The portion of receipts collected in excess of the amount of anticipated reimbursements apportioned by OMB is not considered available in the current year. These receipts, totaling \$3,158,882 at September 30, 2007, will become available for obligation as needed and apportioned in the future.

B. Undelivered Orders

Undelivered Orders - Unpaid	\$ 12,345,322
Undelivered Orders - Paid	<u>-</u>
Total - Undelivered Orders	\$ <u>12,345,322</u>

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Required Supplementary Stewardship Information
(Unaudited)

September 30, 2007

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Stewardship Investments – Research and Development
(Unaudited)

September 30, 2007

		Process Development	Applied Research	Total Research and Development Expense
Fiscal year ended September 30:				
2003	\$	1,825,019	\$ 2,435,572	\$ 4,260,591
2004		862,201	1,081,224	1,943,425
2005		171,945	6,219	178,164
2006		256,099	100,000	356,099
2007		437,002	-	437,002
Total	\$	<u>3,552,266</u>	<u>\$ 3,623,015</u>	<u>\$ 7,175,281</u>

Basis of Presentation

The Isotope Program's (the Program) process development and applied research include all costs for these activities that are intended to increase or maintain national economic productive capacity or yield other future benefits. These investments support the development of new or improved products and processes with the expectation of enhancing isotope production, services, and delivery application systems to meet future demand for research and medical isotopes. Discussed below are accomplishments and contributions from the Program that contribute to the Department of Energy's *Energy Security* Strategic Theme.

Major Research and Development Programs

(a) Process Development

At Los Alamos National Laboratory (LANL), process improvements in fiscal years 2003 and 2004 included Isotope Production Facility (IPF) targetry physics and chemistry research for the production of strontium-82 and germanium-68. Target development continued in fiscal year 2005, including re-engineering of the target required for the run cycle of the new IPF facility which began operations February 2005. These improvements allow for production of short-lived radioisotopes to support medical diagnosis and treatment and scientific research.

Fiscal year 2004 projects also included the development of process chemistry to separate zirconium-88 and yttrium-88 from a gallium target at Brookhaven National Laboratory (BNL) to enable imaging of yttrium-labeled radiopharmaceuticals.

In fiscal year 2005, Oak Ridge National Laboratory (ORNL) conducted lutetium-177 process development to possibly produce large quantities of high specific activity at a moderate cost. ORNL also established a cGMP (current Good Manufacturing Practices) facility to meet United States (U.S.) Food and Drug Administration requirements and customer specifications. Other improved production methods included BNL processing of irradiated rubidium metal targets for improved strontium-82

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Stewardship Investments – Research and Development
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yields and determination of phosphorous-32 and -33 in rubidium chloride irradiations at LANL for strontium-82 production efficiency.

Fiscal year 2006 funding for development projects included separation and analysis of radium-226 targets and barium-140/lanthanum-140 generator and barium-131 development at ORNL. Funding was provided to BNL to develop a new target for copper-67 that will improve specific activity required for most research purposes while preserving production levels.

Fiscal year 2007 projects included continuation of ORNL lutetium-177 specific activity process improvement funded in fiscal year 2005. Samples were provided to several collaborators for analysis. BNL continued to develop new copper-67 target types and chemistry. Yield and specific activity were measured and appear promising. Based on the strontium-82 production efficiency efforts started at LANL in fiscal year 2005, an exemption to the phosphorous-32 and -33 limits was granted and hot cells have been operating under this exemption through fiscal year 2007. Another BNL project is developing yttrium-86, used for Positron Emission Tomography (PET) imaging, into a more affordable product.

(b) *Applied Research*

In fiscal year 2003, funding was provided for refurbishment activities at LANL's Los Alamos Neutron Science Center (LANSCE) to divert a portion of the main beam and direct it to the new IPF target area for the production of isotopes needed for nuclear medicine research. This research project supported the irradiation/production of radioisotopes and other services needed in medical, diagnostic and therapeutic applications and other scientific research used by Federal and non-Federal entities.

No new research projects were funded in fiscal years 2004 through 2007. However, carryover funding through fiscal year 2006 provided for continuation of prior year research projects such as LANL's refurbishment activities noted above.

Started in fiscal year 2002, the Advanced Nuclear Medicine Initiative (ANMI) funded nine research grants to universities, hospitals, national laboratories, and private organizations to support medical research either by direct support of medical research that uses radioisotopes or indirectly through research into new and improved methods of radioisotope production. One grant researched new ways to measure the efficiency of alpha particles in causing cancer cell death. This initiative resulted in five published articles in professional journals and 12 papers presented at scientific meetings. ANMI also funded five educational grants to foster the growth of needed graduate-level education programs in nuclear medicine by supporting nuclear medicine disciplines at universities and colleges. Since fiscal year 2003, no new funds were requested for the program. However, one research grant and one education grant continued through 2006 using carryover funding from prior years. No activity occurred in fiscal year 2007. All grants are now considered closed.

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For further information, a description of the Department of Energy's isotope production facilities is provided. A table listing the prominently sold isotopes produced by the Isotope Program, as well as their uses and the facilities where they are currently produced, is also provided.

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Isotope Production Facilities

Reactors

The facilities and processes used by the Isotope Program (the Program) offer unique capabilities. For example, Oak Ridge National Laboratory's (ORNL) 85-megawatt High Flux Isotope Reactor (HFIR) provides the world's highest steady-state neutron flux. Neutron currents from the four horizontal beam tubes are also very high. The reactor operates about 9 fuel cycles per year; however, in fiscal year 2007 the reactor only operated for 4 fuel cycles which impacted the Program and required some assistance from foreign suppliers. The HFIR is used primarily for neutron scattering experiments, production of transuranic isotopes, production of lighter commercial and research isotopes, and materials science. Built-in experimental irradiation facilities provide great versatility, significant experimental capabilities, and the means to produce a wide variety of isotopes. Products at this facility include californium-252, used for industrial applications and cancer therapy; and tungsten-188, a promising medical isotope. In addition, byproduct from Pacific Northwest National Laboratory (PNNL) inventory such as strontium-90 can be made available.

Accelerators

Because they have high beam currents and can attain high proton bombarding energies, the large linear accelerators at Los Alamos National Laboratory (LANL) and Brookhaven National Laboratory (BNL) can produce isotopes beyond the reach of the private sector and university system. In this way, the Program complements the well-developed production of isotopes in low energy cyclotrons that are distributed throughout the United States.

The Isotope Production Facility (IPF) at LANL can produce radioisotopes using a 100 million electron volt (MeV) proton beam. The IPF beam is obtained by diverting a portion of the main Los Alamos Neutron Science Center (LANSCE) proton beam down a separate IPF beam line to a target station dedicated for isotope production. LANSCE itself is a half-mile-long linear accelerator that currently delivers 800 MeV hydrogen ions, with beam currents up to 1 milliamperes for H⁺ and 100 microamperes for H⁻. Prior to the completion of IPF, target irradiations were done at LANSCE for approximately 20 to 22 weeks per year in Target Area "A." The IPF, however, operates up to 8 months each year largely due to a dedicated beam line and target station.

The sites' three major products include germanium-68, a calibration source for Positron Emission Tomography (PET) scanners; strontium-82, the parent of rubidium-82 that is used in cardiac PET imaging; and sodium-22, used medically in neurological research and commercially as a radiation source.

Calutrons

The Beta-3 Calutron Facility at ORNL Y-12 is no longer needed and has been placed in standby. The Program has been working with the Office of Environmental Management (EM) and ORNL

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to phase out the Calutrons building and minimize costs to the Program until it can be transferred to EM.

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Prominently Sold Isotopes and Their Uses

ISOTOPE	SOME IMPORTANT USES	PRODUCTION SITE(S)
Actinium/Ac-225	Research isotope. Generator of bismuth-213 used for targeted alpha therapy. Used to treat variety of cancers including acute myelogenous leukemia and non-Hodgkin's lymphoma.	ORNL
Aluminum/Al-26	Used as a tracer to study aluminum uptake in mice as high concentrations of aluminum in the brain have been found associated with Alzheimer's disease. Also used as tracer to study effects of acid rain. Acid rain leaches aluminum from soils. The aluminum finds its way into ground water, lakes, and streams leading to fish kills and other harmful effects.	LANL
Arsenic/As-73	Research isotope used as a biomedical tracer for arsenic uptake and retention.	LANL
Calcium/Ca-42*	Used with Ca-44 in human calcium retention studies. Other stable isotopes of calcium are used to study bone growth and nutrition.	ORNL
Californium/Cf-252	Used in brachytherapeutic treatment of cervical cancer. Also used as a neutron source to start up reactors, detect presence of nitrogen-based chemical explosives, and analyze sulfur content of petroleum.	ORNL
Cadmium/Cd-109	Used to induce X-ray emission in coal and other materials such as metal alloys for quantitative and qualitative analysis. Such information leads to cleaner burning coals. Also target for production of silver-109m used in short-term medical imaging.	LANL; BNL

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ISOTOPE	SOME IMPORTANT USES	PRODUCTION SITE(S)
Cadmium/Cd-112*	Accelerator target for Indium-111 (In-111) production. In-111 is a gamma emitter used to image renal function in kidneys and tumors of the liver and pancreas.	ORNL
Copper/Cu-67	Research isotope. Beta emitter with relatively low gamma emission. Used as an antibody label for targeted cancer therapy.	LANL; BNL
Dysprosium/Dy-163*	Research isotope used in accelerators to generate neutrinos.	ORNL
Gallium/Ga-69*	The most abundant isotope of gallium, it is used to produce a highly focused ion beam used to engrave, mill, or etch nanostructures on various materials. Used widely in the semiconductor field.	ORNL
Germanium/Ge-68	Used as a positron source to calibrate Positron Emission Tomography (PET) scanners that are widely used in medical research and cancer imaging.	LANL; BNL
Helium/He-3*	Commercially used in Helium-Lithium (HeLi) and Helium-Neon (HeNe) lasers. Possible fuel source for fusion reactors. Used as a research isotope to study properties of superfluids.	SRS
Hydrogen/H-2 (deuterium)	Used commercially to make deuterium lamps that are used in ultraviolet (UV) spectroscopy. Research isotope used in isotope labeling studies to better understand progress of chemical reactions.	ORNL

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ISOTOPE	SOME IMPORTANT USES	PRODUCTION SITE(S)
Iron/Fe-54*	Target for radioisotope Fe-55 production.	ORNL
Iron/Fe-55	Used as a tracer in iron absorption and retention nutrition studies.	ORNL
Iron/Fe-57*	Research isotope used to study solid state physics with Moessbauer spectroscopy.	ORNL
Iron/Fe-58*	Least abundant isotope of iron. Used as a stable biological tracer when use of iron radioisotopes is not permissible. Detected via mass spectrometry. When patient levels of this isotope are above the natural trace amount, then biologic pathway and retention of iron is revealed.	ORNL
Lead/Pb-204*	Target for lead-205 production.	ORNL
Lithium/Li-6*	Neutron capture therapy research. This isotope has a high affinity for capturing neutrons. By providing patients with drugs made from lithium-6 that target tumors, patients can then be irradiated with neutrons that activate the lithium. The activated lithium then decays and emits radiation that kills the tumor cells.	ORNL
Lutetium/Lu-176*	Reactor target for Lu-177 production, a beta emitter used to label monoclonal antibodies for the treatment of lung cancer, ovarian cancer, etc. Decays with an accompanying gamma photon so that it can be simultaneously used for therapy and imaging.	ORNL

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ISOTOPE	SOME IMPORTANT USES	PRODUCTION SITE(S)
Nickel/Ni-61* Ni-62*	Stable reactor targets for radioisotope production, including Ni-63.	ORNL
Nickel-63/Ni-63	Beta emitter used for detection of explosives in homeland defense initiatives and as a power source for remote instrumentation.	ORNL
Rubidium/Rb-87*	Used as an "atomic clock" in telecommunication devices to coordinate incoming and outgoing signals. Here regarded as "stable" because naturally occurring and has long half-life.	ORNL
Samarium/Sm-152*	Reactor target for Sm-153 production, a beta emitter used in targeted therapy to relieve pain due to bone cancer metastases.	ORNL
Selenium/Se-75	Gamma radiography source.	ORNL
Silicon-32/Si-32	Used as a radioactive tracer to measure silicon uptake by oceanic siliceous diatoms. These diatoms carry on photosynthesis and therefore fix carbon taken up from atmospheric carbon dioxide. Their carbon to silicon ratio determines how fast they remove atmospheric carbon. The study of these diatoms sheds light on possible trends in global warming.	LANL

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ISOTOPE	SOME IMPORTANT USES	PRODUCTION SITE(S)
Sodium-22/Na-22	A radiotracer used to study sodium metabolism in the skeleton. Also used as a calibration source.	LANL
Strontium/Sr-82	Generator of rubidium-82 (Rb-82). Rb-82 is a positron emitter used by PET for cardiac imaging. Given intravenously, it follows the flow of blood through the heart.	LANL; BNL
Strontium/Sr-85	Environmental tracer for strontium-90 uptake in plants, migration in soils and sediments, etc.	LANL; BNL
Strontium/Sr-84* Sr-88*	Reactor target for Sr-89 production.	ORNL
Strontium-89/Sr-89	A bone seeker, this beta emitter is used to relieve painful skeletal metastases associated with prostate and breast cancers. Administered as strontium chloride.	LANL
Strontium/Sr-90	Used as a nuclear battery to power remote equipment on light houses and satellites. Also used as a generator of yttrium-90, a beta emitter used to treat cancer.	PNNL
Thallium/Tl-203	A target for accelerator production of thallium-201 (Tl-201), which is used in cardiac imaging.	ORNL
Tungsten/W-188	Generator of rhenium-188 (Re-188) that is used to prevent re-closure (restenosis) of coronary arteries following heart surgery. Also used as a monoclonal antibody label and to relieve bone cancer pain.	ORNL

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ISOTOPE	SOME IMPORTANT USES	PRODUCTION SITE(S)
Uranium/U-234	Used to detect neutrons and to control instrumentation.	ORNL
Xenon/Xe-124* Xe-126*	Reactor targets used for making xenon radionuclides. Also used for tagging reactor fuel rod assemblies.	ORNL
Xenon/Xe-127 Xe-133	These isotopes are ventilation agents used in lung ventilation/perfusion imaging studies. As gases they are used to image inhalation pathways in the lungs. Perfusion agents, on the other hand, such as technetium-99m (Tc-99m), are administered intravenously to image blood circulatory pathways in the lungs. Disagreements between the two examinations may reveal dysfunctional regions within the lungs.	BNL
Yttrium-90/Y-90	Daughter from the decay of strontium-90. A beta emitter used in cancer therapy.	PNNL
Zinc/Zn-66* Zn-68* Zn-70*	Reactor targets for the production of gallium-67.	ORNL
Zirconium/Zr-90* Zr-92* Zr-94*	Irradiation targets and research.	ORNL

*Separated stable isotopes; all others are radionuclides.