United States Government

Department of Energy

memorandum

DATE: February 3, 1997

REPLY TO

ATTN OF: IG-30

SUBJECT: Isotope Production and Distribution Program's Fiscal Year 1996 Financial Statement Audit (ER-FC-97-01)

TO: Director, Office of Nuclear Energy, NE-1

The attached report presents the results of the independent certified public accountants' audit of the Isotope Production and Distribution Program's (Isotope) financial statements as of September 30, 1996. The auditors have expressed an unqualified opinion on the 1996 statement of financial position and the related statements of operations and changes in net position and cash flows.

The 1996 financial statement audit was made under provisions of the Inspector General Act (5 U.S.C. App.), as amended, the Government Management Reform Act (31 U.S.C. 3515), and Office of Management and Budget implementing guidance. The auditor's work was conducted in accordance with generally accepted government auditing standards. To fulfill our audit responsibilities, we contracted with the independent public accounting firm of KPMG Peat Marwick LLP (KPMG) to conduct the audit for us, subject to our review.

The auditors' report on Isotope internal control structure disclosed no new reportable conditions that could have a material effect on the financial statements. The report did, however, disclose a reportable condition reported in Fiscal Years 1995 and 1994 that had not been resolved during 1996. Isotope program management concurred with the recommendation regarding the unresolved condition and stated that corrective actions were implemented on October 1, 1996, to resolve this reportable condition. The auditors also considered the overview and performance measure data for completeness and material consistency with the basic financial statements. The auditors' report on compliance with laws and regulations disclosed no instances of material noncompliance.

During the course of the audit, KPMG also identified other matters which, although not material to the financial statements, nevertheless, warrant management's attention. These items are fully discussed in a separate letter to management.

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We believe that the financial statements, together with KPMG's opinion and our review of that work, provide Isotope management and the Department's Chief Financial Officer with a basis for evaluating Isotope's financial position and results of operations for the period audited.

In accordance with DOE Order 2320.2B, "Establishment of Departmental Position on Inspector General Reports," as amended by the October 11, 1994, memorandum on "Implementing Guidelines for Streamlining Pilot," no further action is required.

We appreciate the cooperation of your staff during the review.

Gregory H. Friedman
Deputy Inspector General
for Audit Services

Attachment

cc: Director, Office of Civilian Reactor Development, NE-40
Director, Isotope Production and Distribution Division, NE-46
Manager, Eastern Regional Audit Office, IG-36

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KPMG

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**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY
ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM**

Financial Statements

September 30, 1996 and 1995

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

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**U.S. DEPARTMENT OF ENERGY
ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM
FISCAL YEAR 1996 FINANCIAL STATEMENT**

OVERVIEW

Introduction

The charter of the Department of Energy (DOE) Isotope Production and Distribution Program (Isotope Program) covers the production and sale of radioactive and stable isotopes, associated byproducts, surplus materials such as lithium, and related isotope services. Services provided include, but are not limited to, irradiation services, target preparation and processing, source encapsulation and other special preparations, analyses, chemical separations, and leasing of stable isotopes for research purposes. Isotope Program products and services are sold worldwide for use in a wide variety of research, development, biomedical, and industrial applications.

The Isotope Program reports to the Director of the Office of Nuclear Energy, Science and Technology. The Isotope Program operates under a revolving fund, established by the Fiscal Year 1990 Energy and Water Appropriations Act (Public Law 101-101), and maintains financial viability by earning revenues from the sale of isotopes and services and through annual appropriations. The Fiscal Year 1995 Energy and Water Appropriations Act (Public Law 103-316) modified predecessor acts to allow prices charged for Isotope Program products and services to be based on production costs, market value, the needs of the research community, and other factors. The Isotope Program functions as a business; however, prices set for small-volume, high-cost isotopes that are needed for research may not achieve full-cost recovery.

Isotope Program costs are financed by revenues from the sale of isotopes and services and through payments from the isotope support decision unit, which was established in the DOE Fiscal Year 1995 Energy, Supply, Research, and Development appropriation. The isotope decision unit finances production and processing of unprofitable isotopes that are vital to the national interest.

The Department produces isotopes when no domestic or private sector capability exists; where unique Government production facilities are needed such as nuclear reactors and associated hot cells, particle accelerators, and isotope enrichment facilities; or where other productive capacity is insufficient to meet U.S. needs. The Department encourages private sector investment in new isotope production ventures and will sell or lease its existing facilities and inventories for commercial purposes.

The Isotope Program has two primary missions. The first is to produce and distribute certain isotopes for research and development, medical diagnostics and therapy, national defense, and other applications that are needed to meet the national interest or support the Nation's health care system. The second mission is to produce and distribute other isotopes that are in commercial demand on a businesslike basis.

These missions place the Isotope Program in a challenging position. On one hand, it must provide isotopes for research at prices that provide a reasonable return to the U.S. Government, but do not discourage their use. On the other hand, it must sell commercial isotopes on a cost-recovery basis. Thus, the Isotope Program must constantly balance demand, market conditions, societal benefits, and its determination to operate at the lowest possible cost to U.S. taxpayers in selecting which isotopes should be supplied.

As the range of available isotopes and recognized uses has grown, isotope applications have become vital to continued progress in medical research and practice, new industrial processes, and scientific methods. Among the best known of these isotopes and their uses are technetium-99m and thallium-201, used for medical imaging; iridium-192, used for nondestructive testing; cobalt-60, used for medical sterilization and teletherapy applications; americium-241, used in smoke detectors; and helium-3, used for neutron detectors. There are also hundreds of highly valuable, but less well-known, applications. The existence of certain industries such as medical imaging by emission tomography, nondestructive testing, and radiation sterilization, is dependent on the ready availability of isotopes.¹ Isotopes are particularly important as tools in medical research, diagnostics, and treatment. One of every three persons admitted to U.S. hospitals undergoes a diagnostic or therapeutic medical procedure that employs isotopes. The use of isotopes in nuclear medicine represents a \$2 billion per year industry in the United States alone.

An adequate supply of medical and research isotopes produced by either domestic or foreign sources, is essential to maintain effective diagnosis, treatment, and research capabilities for the Nation's health care system and to support basic research and industrial applications that contribute to national economic competitiveness. The Department is committed to ensuring a reliable supply of both stable and radioactive isotopes for domestic application. The DOE Isotope Program supports this commitment by maintaining a strong organizational and financial basis for the Department's isotope production and distribution activities.

Production Processes and Facilities

Isotopes are atoms of an element that have the same atomic number, but different atomic masses. Isotopes may be either stable or radioactive. Stable isotopes are forms of elements that do not decay or emit radiation. Although they occur in nature, many are quite rare. To make stable isotopes useful for various applications, they are separated and enriched primarily through electromagnetic separation (calutrons), thermal diffusion, or cryogenic distillation. Radioactive isotopes (radioisotopes) may occur naturally, but many are produced in reactors through neutron absorption followed by radioactive decay. Other radioisotopes are produced in an accelerator by bombarding a material with charged atomic particles and, subsequently, radioactive decay. The

¹ See Supplemental Financial and Management Information, pg. 28-31: *Prominently Sold Isotopes and Their Uses.*

choice of which method to use depends on production efficiency, cost, quantity needed, technical capability of equipment, and other factors. In some cases, isotopes are extracted from the waste byproducts of Weapons Program activities.²

The DOE Isotope Program provides three major categories of isotopes: radioisotopes, electromagnetically (EM) enriched stable isotopes, and non-EM enriched stable isotopes. Isotope products and services are sold by the DOE site that produces and/or supplies the product or service. Although the Isotope Program directs and oversees production and sale of its products and services, other DOE offices manage the production facilities for many other programs, activities, or needs. Since the Isotope Program is a user of DOE facilities and operates similar to the DOE Work-for-Others Program, costs associated with decontamination and decommissioning of DOE facilities, particularly legacy costs, are the responsibilities of other DOE programs. Cleanup costs directly attributable to isotope processing, however, are borne by the Isotope Program.

Facilities and separation and production processes used by the Isotope Program include reactors, accelerators, calutrons, chemical exchange, and thermal diffusion. Radioisotopes originate from a variety of DOE sites, including the Idaho National Engineering Laboratory (INEL), Los Alamos National Laboratory (LANL), Brookhaven National Laboratory (BNL), Pacific Northwest National Laboratory (PNNL), and Oak Ridge National Laboratory (ORNL). EM-enriched stable isotopes are separated in ORNL's Electromagnetic Isotope Enrichment Facility (calutrons). Until termination of Isotope Program production activities on October 1, 1996, non-EM enriched stable isotopes were produced at EG&G Mound Applied Technologies (Mound). The Mound facility was transferred to the DOE Office of Environmental Restoration and Waste Management (EM) for decontamination and decommissioning.

The decision to terminate Isotope Program operations at the Mound facility was made after careful analysis of economic conditions, available products, and savings from transferring inventories to another isotope production site. ORNL was the most cost-effective choice for consolidation, and sales from the Isotope Program's inventories of non-EM enriched stable isotopes are now being conducted there. This will result in cost savings to the Isotope Program of approximately \$500,000 annually.

In some cases, the facilities and processes used by the Isotope Program offer unique capabilities. For example, ORNL's 85-megawatt High Flux Isotope Reactor (HFIR) provides the world's highest steady state neutron fluxes. Neutron currents from the four horizontal beam tubes are also very high. Transuranic isotopes are the HFIR's primary product. In addition, ORNL's built-in experimental irradiation facilities provide the versatility required to produce a wide variety of isotopes, as well as significant experimental capabilities.

Other unique ORNL facilities include the electromagnetic calutrons used to produce EM-enriched stable isotopes. Only the former Soviet Union has a similar large-scale facility capable of separating isotopes with the same atomic number and different mass weights. During

² Yttrium-90, for example, is extracted from strontium-90, a byproduct of plutonium production.

this process, mixed isotope material is vaporized (heated), and then ionized. The ionized particles are accelerated, and their trajectories are bent by a magnetic field. The lighter particles separate from the heavier particles as they travel in an arc, and are deposited on collectors from which they are removed, chemically purified, and placed in inventory. ORNL's calutrons operate periodically to maintain an appropriate inventory of EM-enriched stable isotopes. They have operated continuously since January 1995.

The 250-megawatt Advanced Test Reactor (ATR) at INEL offers 18 major locations for experimental or radiation work. This reactor is unique in that operators can adjust the local power and flux at each of these locations to provide an unusually high degree of flexibility for isotope production or experimental research. The three most important isotopes produced at the ATR are iridium-192, used in industrial radiography; cobalt-60, used in food sterilization and cancer treatment; and nickel-63, used as a beta power source, e.g., gas sensing device. On October 1, 1996, isotope production activities at INEL were commercialized and are addressed in the section on privatization below.

The Isotope Production Facility at LANL produces radioisotopes by using the primary proton beam and neutrons from the beam stop of the Los Alamos Neutron Science Center (LANSCE), a half-mile-long accelerator that delivers medium energy protons. The unique characteristics of the LANSCE accelerator include a high energy, high beam current that allows production of higher quality radioisotopes, as well as exotic radioisotopes that cannot be produced in other facilities. The site's three major products include germanium-68, used as a calibration source for Positron Emission Tomography (PET) scanners; strontium-82, the parent of rubidium-82, which is used in cardiac PET imaging; and sodium-22, a positron emitter used in neurologic research.

The LANSCE facility is operated and funded by the DOE Office of Defense Programs (DP). Since transfer of landlord responsibilities for this facility to DP, LANSCE's future is now more certain. Funding for fiscal year 1997 has been appropriated and fiscal year 1998 funding is included in the Department's Congressional Budget. The Isotope Program will continue production of accelerator isotopes at this facility during fiscal year 1997.

At BNL, the Brookhaven Linear Isotope Producer (BLIP) currently operates about 20 weeks per year and produces, among other isotopes, strontium-82, germanium-68, and copper-67. Isotopes produced at BNL are used in medical diagnostics. The BLIP facility utilizes the excess beam of a linear accelerator that injects 200 megavolt protons into the 33 gigavolt Alternating Gradient Synchrotron (AGS).

Program Performance

Privatization

The Department's overall goal for the Isotope Program is to reduce the costs of producing and delivering isotope products and services to its customers while increasing the Isotope Program's efficiency and reliability. To meet this goal, the Isotope Program is evaluating opportunities for the private sector to co-fund or invest in new ventures and will divest itself of any activities that

can be operated by the private sector. The Isotope Program also will assist industry with understanding Government regulations and overcoming legal obstacles that impede the privatization of isotope production and services.

In December 1995, a request for expression of interest was published in the Federal Register and Commerce Business Daily to encourage privatization of isotope production and distribution activities. On February 13, 1996, a public information meeting was held at the DOE site in Germantown, Maryland, to discuss and solicit Expressions of Interest (EOI) in privatizing isotope production and related activities. The meeting was attended by more than 70 participants from private industry. Industry concerns discussed during the meeting included protection of proprietary information, waste disposal, regulatory responsibilities, and the lengthy processing time required for Requests for Proposals. Expressions of Interest in privatizing DOE isotope production and related activities were due March 29, 1996.

As of April 8, 1996, 30 EOIs had been received. These EOIs have been reviewed by the Isotope Program staff, with support from other DOE offices. Based on this first review, five specific activities have been identified for privatization. Other activities that have a privatization potential will be identified during a second review.

Requests for Proposals (RFPs) for the first five identified activities will be prepared and published in the Commerce Business Daily by September 1997. In addition, the Isotope Program will hold a series of meetings to provide industry with further information concerning DOE's requirements for responding to the RFPs. Privatization of some Isotope Program activities will result in a decrease in annual congressional appropriations. To further assist private industry in assuming its isotope production activities, at least three Cooperative Research and Development Agreements (CRADAs) will be established by October 1997.

Other privatization activities include commercialization of medical and industrial isotope production at INEL. On October 1, 1996, Lockheed Martin Idaho Technologies Company, the INEL management and operating contractor, awarded a subcontract to MAC Isotopes, LLC, to operate the Test Reactor Area Hot Cells for isotope production and sales. This commercialization initiative could save the Government approximately \$1 million annually while continuing to meet customer needs.

Another means of privatizing Isotope Program activities is outsourcing. The Isotope Program will continue to perform cost/benefit analyses of activities that could be outsourced to private industry (e.g., target fabrication).

Program Planning

The Isotope Program issued its Five-Year Business Plan to associated sites and field offices in May 1996. This Five-Year Business Plan communicated the goals, objectives, strategies, and supporting activities established by management, as well as the key milestones and performance

indicators used to measure the Isotope Program's success. The plan will be updated annually to incorporate site-specific information that corresponds to the goals and objectives described in the plan.

Cost Savings Initiative

With departmental activities shrinking, there will be less sharing of facility costs between DOE programs. This, together with the increasing cost of ensuring environmental, safety, health, and transportation safeguards requirements, will continue to challenge the Isotope Program's efforts to contain costs and stabilize prices. The activities listed in the supplemental³ comprise the near-term Isotope Program activities in this area. The most noteworthy study was to develop ways of reducing the cost of isotope production activities at ORNL at a target cost savings of 40 percent.

Customer Service

The Isotope Program's data bank includes hundreds of customers. The current customer base includes major pharmaceutical companies such as Amersham International, Bristol-Myers Squibb, Du Pont Merck, and Mallinckrodt Medical, Inc.; industrial users such as Spectra Gases, Westinghouse Electric Corporation, and Industrial Nuclear Company; and hundreds of researchers at national laboratories, private companies, and universities. A total of 334 customers were serviced in fiscal year 1996, resulting in 1,988 shipments.

Since Isotope Program sales are not static, customers served and deliveries made are influenced by a number of external and international factors, including production and processing cycles, diagnostic and teletherapy procedures, research, and, of course, competition. Ten formal customer complaints and 16 formal compliments were received in fiscal year 1996. More than 93 percent of the isotopes ordered from the Isotope Program were delivered to customers on schedule. The slip from 95 percent in fiscal 1995 to 93 percent in fiscal year 1996 was due to a large extent to inclement weather. Most other delays involved deliveries of reactor-produced isotopes and were caused by changes in operating schedules and circumstances related to other programs.

In addition, the Isotope Program generally provides a high quality product as evidenced from customer compliments. Of the total amount of 1988 deliveries, the program experienced a few defective products during fiscal year 1996 that are worth noting. First, there was a failed target at BNL due to impurities in the rubidium chloride material. Costs for identifying and correcting the problem amounted to over \$200,000 resulting in lost sales. INEL experienced contamination problems with the processing of iridium. An iridium process improvement team was appointed immediately. Prior to the next processing campaign, not only had the processing been improved, but better material had been designed to put inside the special form shipping containers to reduce oxidation. ORNL reported Ir-192 pellets were stuck in the special form capsule. The materials were returned from the customer for examination and credit was issued. A replacement purchase

³ See page 24 of Supplemental Financial and Management Information

was made.

Process Development

One highly significant ongoing Isotope Program initiative is the establishment of a U.S. capability for production of molybdenum-99 (Mo-99) and related medical isotopes. Mo-99 is a precursor of technetium-99 (Tc-99m), an isotope that is used in over 36,000 medical procedures each day in the United States alone. At present, there is no U.S. source for Mo-99 and other related medical isotopes that are essential to the Nation's health care and research needs. Domestic requirements for Mo-99 are currently supplied by a single aging reactor in Canada.

To ensure a reliable U.S. source of supply of this vital isotope, the Department has established a medical isotopes production project focused on producing Mo-99. In relation to this project, the Department began preparation of an environmental impact statement pursuant to the National Environmental Policy Act in fiscal year 1995. This environmental impact statement has been completed and, on September 11, 1996, the Department announced its decision to produce Mo-99.

Sandia National Laboratories' Annular Core Research Reactor (ACRR), a 2 megawatt, pool-type research reactor, Sandia's nearby hot cell facility, and LANL's Chemistry and Metallurgy Research Facility will be used to produce the isotope. The initial Mo-99 quality samples production runs began in October 1996. U.S. Food and Drug Administration approval of the Mo-99 will be sought in early 1997. By the end of fiscal year 1997, the facilities will be able to provide about 10 percent of the U.S. supply on a sustained basis. Eventually, these facilities could provide 100 percent of the U.S. supply. It should be noted that the fiscal year 1998 Office of Management and Budget passback did not include funding for Mo-99. This action is being appealed by the Department.

Another initiative involves the use of radioisotopes that emit alpha particles. Early results achieved by various cancer research institutions suggests that alpha-emitting radioisotopes may offer several advantages in treating certain cancers. The Isotope Program will provide the alpha-emitting radioisotopes needed to continue this preliminary medical research. If further research is approved and the results are promising, the Isotope Program will develop improved methods of extracting these valuable radioisotopes.

Financial Performance

Isotope sales projections for fiscal year 1996 were \$14 million, while actual sales were \$16.8 million. Isotope Program financial highlights for the last three years are listed below.

	<u>1996</u>	<u>1995</u>	<u>1994</u>
Total Revenues	\$16,771,930	\$15,401,777	\$10,039,428
Cost of Sales and Services	<u>13,021,259</u>	<u>10,510,743</u>	<u>8,154,381</u>
Gross Profit	\$ 3,750,671	\$ 4,891,034	\$ 1,885,047
Gross Profit Percentage	22.4%	31.8%	18.8%

Total fiscal year 1996 sales increased \$1.4 million above total fiscal year 1995 sales.⁴ This increase was due to long-term contracts for various isotopes established in fiscal year 1995 and other market factors. Sales in fiscal year 1996 were the highest since fiscal year 1989, before the inception of the revolving fund. The isotopes that contributed most of the revenues were thallium-203, helium-3, strontium-82 and -88, germanium-68, iridium-192, and americium-241. For fiscal year 1997, sales will decline because of privatization of some isotopes and anticipated decreases in demand due to changes in product mix and newly aggressive foreign competition. The decline in gross profit percentage of 9.4 percent was attributed to higher INEL and PNNL operating expenses due to idle hot cell and processing capacity.

Market Pace

Historically, the worldwide isotope market has been characterized by high barriers to entry, resulting in a relatively small number of producers. In spite of the barriers, the number of producers entering the worldwide market for selected major isotopes is growing. For example, due to a shortage of Mo-99 suppliers, isotope producers such as DOE, Mallinckrodt, and Nordion International are engaged in programs to establish new Mo-99 facilities.

Most of the world's isotope producers are Government-owned and operated. Worldwide demand for most isotopes is limited, but growing. World production capacity for many isotopes exceeds demand; as a result, direct competition among isotope producers is fierce.

The Isotope Program is enhancing its marketing methods to fully address customer requirements and to forecast future trends. This is being done through frequent interactions between customers and program staff, particularly the marketing manager; data obtained from Isotope Program business reply cards; and coordination of isotope activities with stakeholders in the isotope community, including other Federal Agencies. Research on market sizes, pricing pressures, competition, and customer feedback also is being obtained through independent surveys and studies,⁵ as well as program management assessments.

Financial Statements Limitations

The following financial statements report the financial position and results of the Isotope Program's operations. The statements were prepared using the Isotope Program's books and records, and in accordance with the formats prescribed by the Office of Management and Budget. Although these statements are prepared from the same books and records, they are different from

⁴ See Figure 1, *DOE Isotope Sales for Seven Years*, page 26.

⁵ *The Untold Story: Economic and Employment Benefits of the Use of Radioactive Materials*, published by Organizations United for Responsible Low-Level Radioactive Waste Solutions, 1994, and *Isotopes for Medicine and the Life Sciences*, published by the Institute of Medicine, 1995.

the financial reports used to monitor and control budgetary resources.

The statements should be read with the realization that they are for DOE purposes; that unfunded liabilities reported in the financial statements cannot be liquidated without enactment of an appropriation; and that payment of all liabilities other than for contracts can be abrogated by the DOE entity (the Isotope Program).

Independent Auditors' Report on Financial Statements

Office of Nuclear Energy
United States Department of Energy:

We have audited the accompanying statements of financial position of the United States Department of Energy's Isotope Production and Distribution Program as of September 30, 1996 and 1995, and the related statements of operations and changes in net position, and cash flows for the years then ended. These financial statements are the responsibility of the management of the Isotope Production and Distribution Program. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with generally accepted auditing standards; *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin 93-06, *Audit Requirements for Federal Financial Statements*. Those standards 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 examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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 Production and Distribution Program as of September 30, 1996 and 1995, the results of its operations and changes in net position, and cash flows for the years then ended on the basis of accounting described in note 1.

In accordance with *Government Auditing Standards*, we have also issued reports dated December 13, 1996 on the Isotope Production and Distribution Program's compliance with laws and regulations and on our consideration of its internal control structure.

Our audits were made for the purpose of forming an opinion on the basic financial statements taken as a whole. The information presented in management's *Overview and Supplemental Financial and Management Information* is not a required part of the basic financial statements but is supplementary information required by OMB Bulletin 94-01, *Form and Content of Agency Financial Statements*. We have considered whether this information is materially inconsistent with the basic financial statements. Such information has not been subjected to the auditing procedures applied in the audits of the basic financial statements and, accordingly, we do not express an opinion on it. Performance information included in management's *Overview and Supplemental Financial and Management Information* is addressed in our auditors' report on the internal control structure in accordance with OMB Bulletin 93-06.

This report is intended for the information of the management of the Isotope Production and Distribution Program and the United States Department of Energy. This restriction is not intended to limit the distribution of this report, which is a matter of public record.

December 13, 1996

KPMG Peat Marwick LLP

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Statements of Financial Position

September 30, 1996 and 1995

<u>Assets</u>	<u>1996</u>	<u>1995</u>
Entity assets:		
Intragovernmental assets:		
Fund balance with Treasury	\$ 17,868,862	13,158,126
Accounts receivable, net (note 3)	584,729	269,476
	<u>18,453,591</u>	<u>13,427,602</u>
Governmental assets:		
Accounts receivable, net (note 3)	1,749,747	2,149,924
Advances and prepayments	-	2,500
	<u>1,749,747</u>	<u>2,152,424</u>
Inventories held for sale, net (notes 2 and 4):		
Radioisotopes	2,084,811	1,852,127
Stable isotopes	4,525,918	2,367,883
	<u>6,610,729</u>	<u>4,220,010</u>
Total inventories held for sale		
	<u>6,610,729</u>	<u>4,220,010</u>
Equipment, net (note 5)	1,440,690	701,410
	<u>1,440,690</u>	<u>701,410</u>
Total entity assets	<u>\$ 28,254,757</u>	<u>20,501,446</u>
 <u>Liabilities and Net Position</u>		
Liabilities covered by budgetary resources:		
Intragovernmental liabilities:		
Accrued expenses	55,042	108,679
Liabilities not covered by budgetary resources:		
Intragovernmental liabilities:		
Accrued leave	89,536	79,511
Governmental liabilities:		
Customer advances	148,595	91,990
	<u>148,595</u>	<u>91,990</u>
Total liabilities	<u>293,173</u>	<u>280,180</u>
Net position:		
Balances:		
Invested capital (note 1 (c))	41,618,336	41,618,336
Cumulative results of operations	(13,656,752)	(21,397,070)
	<u>27,961,584</u>	<u>20,221,266</u>
Total net position		
	<u>27,961,584</u>	<u>20,221,266</u>
Commitments and contingencies (notes 9, 10, and 11)		
Total liabilities and net position	<u>\$ 28,254,757</u>	<u>20,501,446</u>

The accompanying notes are an integral part of these statements.

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY
ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM**

Statements of Operations and Changes in Net Position

Years ended September 30, 1996 and 1995

	<u>1996</u>	<u>1995</u>
Revenues from sales of goods and services:		
To the public:		
Domestic	\$ 7,076,247	7,214,186
Foreign	8,785,660	7,507,630
Total revenues from sales to the public	15,861,907	14,721,816
Intragovernmental sales of goods and services	910,023	679,961
Total revenues from sales of goods and services	16,771,930	15,401,777
Cost of sales and services	(13,021,259)	(10,510,743)
Gross profit from sales	3,750,671	4,891,034
Other financing sources:		
Payments from the isotope support decision unit (note 1 (c))	24,658,000	19,395,000
Total revenues and financing sources, less cost of sales and services	28,408,671	24,286,034
Expenses:		
Program expenses:		
Process development (note 6)	11,706,478	8,367,077
Marketing and customer service	2,944,599	1,718,040
Isotope storage and distribution	3,832,684	3,632,803
General and administrative (note 7)	3,396,405	2,887,719
Total program expenses	21,880,166	16,605,639
Other (revenues) expenses:		
Depreciation of isotope equipment	231,273	206,917
Provision for doubtful accounts receivable	1,422	41,514
Lower of cost or market inventory adjustment (note 4)	(20,311)	306,890
Change in allowance for excessive inventory quantities (note 4)	(634,128)	976,188
Change in estimate of inventory valuation (note 2)	-	1,829,923
Gain on sale of fixed asset	(81,250)	-
Total other (revenues) expenses	(502,994)	3,361,432
Total expenses	21,377,172	19,967,071
Excess of revenues and financing sources over total expenses	\$ 7,031,499	4,318,963

(Continued)

UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Statements of Operations and Changes in Net Position, Continued

Years ended September 30, 1996 and 1995

	<u>1996</u>	<u>1995</u>
Net position, beginning balance	\$ 20,221,266	15,519,764
Excess of revenues and financing sources over total expenses	7,031,499	4,318,963
Non-operating changes (note 8)	<u>708,819</u>	<u>382,539</u>
Net position, ending balance	<u>\$ 27,961,584</u>	<u>20,221,266</u>

The accompanying notes are an integral part of these statements.

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Statements of Cash Flows

Years ended September 30, 1996 and 1995

	<u>1996</u>	<u>1995</u>
Cash flows from operating activities:		
Excess of revenues and financing sources over total expenses	\$ 7,031,499	4,318,963
Adjustments to reconcile (excess) deficiency of revenues over total expenses to net cash used in operating activities:		
Depreciation	231,273	206,917
Provision for doubtful accounts receivable	(699,049)	(179,143)
Non-operating changes	708,819	382,539
Gain on sale of equipment	(81,250)	-
(Increase) decrease in operating assets:		
Accounts receivable	783,973	(748,467)
Inventories, net	(2,390,719)	3,095,352
Advances and prepayments	2,500	(2,000)
Increase (decrease) in operating liabilities:		
Customer advances	56,605	(155,365)
Accrued expenses	(53,637)	14,815
Accrued leave	10,025	62,055
Total adjustments	<u>(1,431,460)</u>	<u>2,676,703</u>
Net cash provided by operating activities	5,600,039	6,995,666
Cash flows from investing activities		
Purchase of equipment	(989,303)	(360,507)
Proceeds from sale of equipment	100,000	-
Net cash used in investing activities	<u>(889,303)</u>	<u>(360,507)</u>
Net increase in cash	4,710,736	6,635,159
Fund balance with Treasury, beginning of year	<u>13,158,126</u>	<u>6,522,967</u>
Fund balance with Treasury, end of year	<u>\$ 17,868,862</u>	<u>13,158,126</u>

The accompanying notes are an integral part of these statements.

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

September 30, 1996 and 1995

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

(a) Basis of Presentation

These financial statements have been prepared to report the financial position and results of operations of the Isotope Production and Distribution Program (Isotope Program, or Program). The statements have been prepared from the books and records of the Isotope Program in accordance with the applicable form and content requirements of Office of Management and Budget (OMB) Bulletin 94-01 and the Program's accounting policies, which are summarized in this note. These statements are therefore different from the financial reports, also prepared by the Program pursuant to OMB directives, that are used to monitor and control the Program's use of budgetary resources.

The United States Department of Energy's (Department) headquarters, field offices, and the management and operating (M&O) contractors operating the Department facilities discussed in note 1(b) record Isotope Program activity in their accounting systems. The M&O contractors integrate their accounting systems with 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 Department accounting practices and procedures. These financial statements are prepared by extracting and adjusting Program-related data from the financial records of the Department and its contractors.

(b) Reporting Entity

The Isotope Program has two primary missions. The first is to produce and distribute certain isotopes for research and development, medical diagnostics and therapy, national defense, and other applications that are needed to meet the national interest or support the Nation's health care system. The second mission is to produce and distribute other isotopes that are in commercial demand on a business-like basis. The Program is a user of Department facilities and provides funding through the Department site offices to 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 offices 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 1(m), the full cost of providing the products and services, including such items as labor, benefits and packaging, is charged to the Program.

Isotope production and related activities are performed at the following sites: Brookhaven National Laboratory (BNL), Upton, New York; EG&G Mound Applied Technologies (Mound), Miamisburg, Ohio; Los Alamos National Laboratory (LANL), Los Alamos, New Mexico; Idaho National Engineering Laboratory (INEL), Idaho Falls, Idaho; Oak Ridge National Laboratory (ORNL), Oak Ridge, Tennessee; and Pacific Northwest National Laboratories (PNNL), Richland, Washington. In addition, the Isotope Program is currently funding process development activities aimed at establishing a United States production capability for molybdenum 99 (Mo-99) and related medical isotopes at the Sandia National Laboratory in Albuquerque, New Mexico. Certain Mo-99 process development activities are also funded at LANL.

(Continued)

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(c) Revolving Fund and Direct Appropriations

The fiscal year 1990 Appropriations Act, Public Law 101-101, established a separate Isotope Program revolving fund with an initial appropriation; inventory on hand at October 1, 1989; and the unexpended balances of previous appropriations for similar activities. The balance of this invested capital is \$41.6 million as of September 30, 1996. As a revolving fund, the Program receives all revenues from the sales of isotopes and related services.

The 1995 Energy and Water Development Appropriation established a new isotope support decision unit in the Department's energy supply, research, and development appropriation. The isotope support decision unit funds a payment into the Isotope Program for the production and processing of those isotopes which, although unprofitable, are in the national interest. During fiscal year 1995, the Program received \$19.4 million of payments from the isotope support decision unit. During fiscal year 1996, the Program received \$24.7 million in payments from the isotope support decision unit.

(d) Basis of Accounting

The Isotope Program uses 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.

The financial statements are prepared in accordance with the following hierarchy which constitutes a comprehensive basis of accounting:

Individual standards agreed to and published by the Joint Financial Management Improvement Program Principals, based upon recommendations from the Federal Accounting Standards Advisory Board.

Form and content requirements included in OMB Bulletin 94-01, *Form and Content of Agency Financial Statements*.

Accounting standards contained in agency accounting policy, procedures manuals, and/or related guidance as of March 29, 1991, so long as they are prevalent practices.

Accounting principles published by authoritative standard setting bodies and other authoritative sources in the absence of other guidance in the first three parts of this hierarchy, to the extent that the use of such accounting standards improves the meaningfulness of the financial statements.

(Continued)

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(e) Pricing Policy

The Isotope Program's prices are based on replacement cost, market value, the needs of the research community, and other factors. Prices set may or may not achieve cost recovery.

(f) Fund Balance with Treasury

Isotope Program cash receipts and disbursements are processed through the United States Treasury. The funds with the Treasury are available to pay current liabilities and to finance authorized purchase commitments.

(g) Allowance for Doubtful Accounts

Accounts receivable have been reduced by an allowance for doubtful accounts. This allowance has been determined based on an analysis of outstanding balances, past experience, and present market conditions.

(h) Inventories

Isotope Program inventories consist of two major categories - radioisotopes and stable isotopes. Only those radioisotopes with a half-life in excess of one year are included in inventory. Periodic entries are recorded to reflect any decay losses. All inventories are valued based on average cost, and are stated at the lower of cost or market value as of September 30, 1996 and 1995. With the exception of the electromagnetic stable isotopes at ORNL, inventory quantities that exceed the total quantity sold during the preceding five years are included in the allowance for excessive inventory quantities. Quantities of electromagnetic stable isotopes at ORNL that exceed the total quantity sold during the preceding five years are written off.

(i) Equipment

The Isotope Program is a user of Department facilities and, as such, does not own or fully control the land, buildings and other assets in which it operates, but rather is charged a fee from the other Department operations. The Program, however, does make equipment purchases as needed for Program operations. Equipment costing more than \$5,000 with an expected life of more than two years is capitalized and depreciated on a straight-line basis over the estimated useful life of the asset.

(j) Customer Advances

Certain customers may be required to make payment in advance of delivery. These advances are recorded as a liability by the Isotope Program; revenue is recognized upon delivery.

(k) Annual, Sick, and Other Leave

Annual leave is accrued when earned, and the accrual is reduced as leave is taken. The accrued annual leave liability is principally long term in nature. Sick leave and other leave are expensed as taken.

(Continued)

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(1) Pensions and Other Retirement Benefits

All permanent Department 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% 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 by the Office of Personnel Management and are not allocated to individual departments and agencies. Reporting such amounts is the responsibility of the Office of Personnel Management.

(m) Material Produced by Other Department Programs

Certain isotopes result as byproducts from production activities of other Department programs. The Isotope Program acts as a marketing and distribution agent for one marketable byproduct. In fiscal years 1996 and 1995, the Program recognized revenue of approximately \$1.3 million and \$1.4 million, respectively, from sales of this isotope, for which there was no production cost basis.

(n) Use of Estimates

Program management has made a number of estimates and assumptions relating to the reporting of assets and the disclosure of contingent liabilities to prepare these financial statements in accordance with the basis of accounting described above. Actual results could differ from those estimates.

(2) Change in Method of Inventory Valuation

During fiscal year 1995, the Isotope Program changed its method of accounting for ORNL electromagnetic stable isotope inventories to reflect revised estimates of the future benefits of these isotopes. Prior to fiscal year 1995, ORNL separately valued all isotopes in inventory and provided allowances for excessive inventory quantities for those isotopes whose future sales were doubtful. In fiscal year 1995, ORNL assigned value to only those isotopes for which a relatively active market exists. ORNL wrote off the costs relating to those isotopes which have a limited market or are used primarily for research purposes, rather than including such costs in the allowance for excessive inventory quantities.

The fiscal year 1995 effect of this change amounted to \$1.8 million. As the effect of the change in method is inseparable from the effect of the change in estimate, the effect of the change has been included in the fiscal year 1995 statement of operations.

(Continued)

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(3) Accounts Receivable

Accounts receivable consist of the following at September 30, 1996 and 1995:

		1996	
		<u>Governmental</u>	<u>Intragovernmental</u>
Accounts receivable		\$ 1,752,695	584,729
Less allowance for doubtful accounts		(2,948)	-
		<u>\$ 1,749,747</u>	<u>584,729</u>

		1995	
		<u>Governmental</u>	<u>Intragovernmental</u>
Accounts receivable		\$ 2,851,921	269,476
Less allowance for doubtful accounts		(701,997)	-
		<u>\$ 2,149,924</u>	<u>269,476</u>

(4) Inventories

Inventories held for sale consist of the following at September 30, 1996 and 1995:

		1996	
		<u>Radioisotopes</u>	<u>Stable Isotopes</u>
Cost		\$ 5,367,519	8,097,224
Less:			
Allowance for excessive inventory quantities		(2,899,949)	(3,206,617)
Valuation adjustment to the lower of cost or market value		(382,759)	(364,689)
		<u>\$ 2,084,811</u>	<u>4,525,918</u>

		1995	
		<u>Radioisotopes</u>	<u>Stable Isotopes</u>
Cost		\$ 5,796,289	5,932,174
Less:			
Allowance for excessive inventory quantities		(3,591,267)	(3,149,427)
Valuation adjustment to the lower of cost or market value		(352,895)	(414,864)
		<u>\$ 1,852,127</u>	<u>2,367,883</u>

(Continued)

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

Certain stable isotopes are on lease to various customers. Lease charges are based on the current sales value of the isotope being leased. In addition, the Isotope Program charges an annual renewal fee of \$3,200 for each isotope leased. Lease revenues for fiscal years 1996 and 1995 were \$151,590 and \$208,756, respectively.

Prior to fiscal year 1995, leased isotopes were valued in the same manner as other stable isotopes at ORNL - all leased isotopes for which the quantity on hand, when combined with the sales pool, was greater than the quantity sold in the preceding five years were considered excessive and included in the allowance. During fiscal year 1995, the net book value of all leased material was written off as a part of the change in method of inventory valuation (note 2).

Activity in the allowance for excessive inventory quantities for fiscal years 1996 and 1995 is as follows:

	<u>Inventories held for sale</u>		<u>Inventories on loan or lease</u>	
	<u>Radioisotopes</u>	<u>Stable</u>	<u>Stable</u>	<u>Total</u>
Balance, September 30, 1994	\$ 2,752,260	37,057,624	598,895	40,408,779
Decrease due to change in method of inventory valuation (note 2)	-	(34,045,378)	(598,895)	(34,644,273)
Current year increase	839,007	137,181	-	976,188
Balance, September 30, 1995	3,591,267	3,149,427	-	6,740,694
Current year (decrease) increase	(691,318)	57,190	-	(634,128)
Balance, September 30, 1996	<u>\$ 2,899,949</u>	<u>3,206,617</u>	<u>-</u>	<u>6,106,566</u>

(5) Equipment

Equipment consists of the following at September 30, 1996 and 1995:

	<u>1996</u>	<u>1995</u>
Shipping casks	\$ 500,000	750,000
Production equipment	1,487,951	498,647
	<u>1,987,951</u>	<u>1,248,647</u>
Less accumulated depreciation	(547,261)	(547,237)
	<u>\$ 1,440,690</u>	<u>701,410</u>

(Continued)

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(6) Process Development Costs

Consistent with fiscal year 1995, the majority of the fiscal year 1996 process development costs relate to the Program's initiative to establish a United States production capability for Molybdenum 99 (Mo-99) and related medical isotopes. Total costs for this initiative during fiscal years 1996 and 1995 were \$10.4 million and \$7.5 million, respectively. An additional \$1.3 million incurred in fiscal year 1996 and \$0.9 million in fiscal year 1995 relate to various research and development projects at other isotope production facilities.

(7) General and Administrative Expenses

General and administrative expenses for the years ended September 30, 1996 and 1995 consist of the following:

	<u>1996</u>	<u>1995</u>
Personal services and benefits	\$ 918,622	783,867
Travel and transportation	49,597	63,145
Contractor and other program expenses	<u>2,428,186</u>	<u>2,040,707</u>
	<u>\$ 3,396,405</u>	<u>2,887,719</u>

(8) Non-Operating Changes

Non-operating changes consist of transfers to offset allocations of site depreciation expense to the Program. Net transfers during the years ended September 30, 1996 and 1995, consist of:

	<u>1996</u>	<u>1995</u>
Ohio Field Office	\$ 101,375	84,208
Albuquerque Operations Office	-	189,651
Oak Ridge Operations Office	606,838	108,680
Idaho Field Office	<u>606</u>	<u>-</u>
	<u>\$ 708,819</u>	<u>382,539</u>

(9) Royalty Agreement

During fiscal 1992, the Department entered into a cooperative agreement with Cintichem, Inc. through which the Department acquired isotope production equipment, technology, and processes to allow the Isotope Program to expand its ability to provide critical medical isotopes to the U.S. nuclear medical community. The terms of this agreement state that the Program will pay Cintichem a four-percent royalty on gross worldwide sales of Mo-99 produced by the Department for a period of five years from the start of Mo-99 production using Cintichem's technology. No Mo-99 has been produced for sale as of September 30, 1996.

(Continued)

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(10) Customer Concentration

The Program has one customer that accounts for over 28% of total fiscal 1996 revenue. The Program has a long-term contract with this customer that expires on December 31, 1997. As of September 30, 1996, this customer had an outstanding accounts receivable balance of approximately \$425,000.

(11) Environmental Costs

Department Order 5820.2A establishes policies and guidance for the decontamination and decommissioning of radioactively contaminated facilities under Department ownership or control. For multiple user facilities, the program office shall determine the decommissioning liability for user program offices based on each program's overall contribution to the contamination, or some other mutually acceptable basis. Consequently, a portion of the decontamination and decommissioning costs related to the facilities at which the Isotope Program conducts operations may be allocable to the program. However, no estimates of the total decontamination and decommissioning costs or the portion applicable to the Isotope Program, if any, are currently available.

**U.S. DEPARTMENT OF ENERGY
ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM
FISCAL YEAR 1996 FINANCIAL STATEMENT**

SUPPLEMENTAL FINANCIAL AND MANAGEMENT INFORMATION

Program Performance Measures

Sales Volume Activity

Isotope Program sales projections are dynamic and can require frequent modification. Early (October 1995) projections for fiscal year 1996 were approximately \$14 million, while actual sales totaled \$16.8 million. Total fiscal year 1996 sales increased \$1.4 million above total fiscal year 1995 sales (see Figure 1, *DOE Isotope Sales for Seven Years*, page 26). The total fiscal year 1996 revenues includes a Canadian company who purchased over 28 percent of all sales from DOE and distributes to U.S. companies. In terms of revenue, stable isotopes outsold radioisotopes by a 1.12:1.00 ratio. [A more detailed breakdown of Isotope Program production categories is shown in Figure 2, *Isotope Sales By Production Category*, page 27.] More than one-half of total sales to the public were made to foreign customers.

Molybdenum-99 Production Development Costs

Molybdenum-99 (Mo-99) is a short-lived isotope with a 66-hour half-life. It is essential to the production of technetium-99m (Tc-99m), an isotope that has applications such as diagnostic studies of the brain, heart, and other organs. Tc-99m is used in more than 70 percent of all nuclear medicine procedures, equal to more than 36,000 procedures each day in the United States alone. The need for multiple supply sources of such short-lived medical isotopes, including an indigenous U.S. source, is the basic motivation for the ongoing initiative to develop domestic production capabilities for Mo-99 and related isotopes.

To ensure a reliable U.S. source of supply of this vital isotope, the Department has established a medical isotopes production project focused on producing Mo-99. In relation to this project, the Department began preparation of an environmental impact statement pursuant to the National Environmental Policy Act in fiscal year 1995. This environmental impact statement has been completed and, on September 11, 1996, the Department announced its decision to produce Mo-99.

Sandia National Laboratories' Annular Core Research Reactor (ACRR), a 2 megawatt, pool-type research reactor, Sandia's nearby hot cell facility, and Los Alamos National Laboratory's Chemistry and Metallurgy Research Facility will be used to produce the isotope. The process for Mo-99 production was demonstrated at these facilities in fiscal year 1995 and improvements to the hot cell facility were made. Mo-99 quality sample production runs began in October 1996 and the product met customer specifications. U.S. Food and Drug Administration approval of the Mo-99 will be sought in early 1997. By the end of fiscal year 1997, the facilities will be able

to provide about 10 percent of the U.S. supply on a sustained basis if sufficient funding is identified. Eventually, these facilities could provide 100 percent of the U.S. supply. Total fiscal year 1996 expense for this project was almost \$10.4 million.

Customer Data and Satisfaction

A total of 334 customers were serviced in fiscal year 1996. Sixteen customers comprised 86 percent of sales. The total number of deliveries/shipments made was 1,988 an increase of over six percent from fiscal year 1995. Of these 1,988 deliveries, 998 were domestic, 786 were foreign, and 204 were intragovernmental. Since Isotope Program sales are not static, customers served and deliveries made are influenced by external and international factors such as production and processing cycles, diagnostic and teletherapy procedures, research, and, of course, competition.

Ten formal customer complaints were received in fiscal year 1996, along with 16 formal customer compliments. More than 90.1 percent of stable isotope orders were shipped by the promised shipping date. In fiscal year 1996, greater than 93.7 percent of the radioisotopes sold by the Isotope Program were delivered as scheduled. Most delays were due to a large extent to inclement weather.

Cost Savings Initiative

With departmental activities shrinking, there will be less sharing of facility costs between DOE programs. This, together with the increasing cost of ensuring environmental, safety, health, and transportation safeguards requirements, will continue to challenge the Isotope Program's efforts to contain costs and stabilize prices. The activities listed below comprise the near-term Isotope Program activities in this area.

- A study to develop ways of reducing the cost of isotope production activities at ORNL is targeted for 40 percent and will be reviewed for approval and implementation in December 1996.
- To further reduce costs at ORNL, most radioisotope processing activities will be consolidated at one designated hot cell facility, which will be managed by the Office of Nuclear Energy, Science and Technology.
- As a means of reducing unit production costs, high-volume, multi-year contracts with current customers will be sought.
- The Isotope Program will reduce nonproduction costs at least five percent annually by leasing excess hot cell capacity, and reassigning, redirecting, or sharing on-site staff that are not fully utilized.

Financial Performance Measures

Profitability

Total fiscal year 1996 sales increased \$1.4 million above total fiscal year 1995 sales. This increase was due to long-term contracts for various isotopes established in fiscal year 1995 and other market factors. The increase in the Isotope Program's fiscal year 1996 sales produced a gross profit of 22.4 percent, as compared to a gross profit of 31.8 percent in fiscal year 1995. The decline in gross profit percentage of 9.4 percent was attributed to higher INEL and PNNL operating expenses due to idle hot cell and processing capacity.

Accounts Receivable Collections

The Isotope Program's net accounts receivable turnover for fiscal year 1996 was 7.1 times, or every 51.4 days.

Inventory Turnover

The Isotope Program has two major inventory categories: radioisotopes and stable isotopes. Generally, because of the short shelf-life of most of the radioisotopes sold by the Isotope Program, a large inventory is not maintained. In addition, some products are purchased as needed from other DOE program inventories. Inventory turnover to sales for capitalized radioisotopes was a satisfactory 1.72 times, based on the average net inventory value during the year. Decrease from 1.96 percent in fiscal year 1995 was due to schedule outages of the ATR which resulted in less production of reactor produced isotopes.

The inventory turnover to sales for stable isotopes was 2.46 times, based on the average net inventory value during the year. This represents an increase from the fiscal year 1995 turnover rate of 0.47 times. The increase resulted from higher thallium-203 and helium-3 sales.

In the aggregate, it should be noted that isotope inventory analysis is difficult because of the wide variety in product types, processes, and lead times.

Figure 1

DOE Isotope Sales For Seven Years

* Includes two large transactions totaling over \$3 million, one to DOE and the other to a commercial organization

Figure 2
DOE Isotope Sales By Production Category

FY 1996 Sales - \$16.8 Million

FY 1995 Sales - \$15.4 Million

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

PROMINENTLY SOLD ISOTOPES AND THEIR USES FISCAL YEAR 1996

<u>ELEMENT/ISOTOPES</u>	<u>IMPORTANT USES</u>	<u>WHERE AVAILABLE</u>
Aluminum/Al-26	Research: Alzheimer's Disease; Acid Rain	Los Alamos - LANSCE
Americium/Am-241	Neutron Source for oil well logging; smoke detectors	Los Alamos - Inventory
Calcium/Ca-42* -43 -44 -46 -48	Research: Nutrition Bone Growth Nucleosynthesis Nuclear Physics	Oak Ridge - Calutrons
Californium/Cf-252	Cancer Therapy (esp. ovarian/cervical cancer); Portable Neutron Sources; Reactor Monitoring/Control	Oak Ridge - HFIR
Cadmium/Cd-109	X-Ray Fluorescence Instrument Calibration; Silver (Ag-109m) Generation (for short- time medical imaging)	Los Alamos - LANSCE
Cadmium/Cd-112*	Accelerator Targets for medical radioisotope prod. (such as In-111 used for physiological studies of soft tumors)	Oak Ridge - Calutrons

* Separated Stable Isotopes; all others are radionuclides.

PROMINENTLY SOLD ISOTOPES AND THEIR USES
FISCAL YEAR 1996

<u>ELEMENT/ISOTOPES</u>	<u>IMPORTANT USES</u>	<u>WHERE AVAILABLE</u>
Cobalt/Co-60	Radiation Sources; Cancer Teletherapy	Idaho - ATR
Copper/Cu-67	Antibody Labeling for cancer therapy & imaging	Los Alamos - LANSCE Brookhaven - BLIP
Dysprosium/Dy-163*	Accelerator Research Target-Neutrino generation	Oak Ridge - Calutrons
Gallium/Ga-69*	Needed in focused ion beam devices for research	Oak Ridge - Calutrons
Germanium/Ge-68	Calibration Sources for PET Equipment; Antibody Labeling	Los Alamos - LANSCE Brookhaven - BLIP
Helium/He-3*	Lasers; Neutron Detectors; Cryogenics	Mound - Inventory**
Hydrogen/H-2* (Deuterium)	Isotopic Labeling; Mass Spectrometry Calibration	Mound - Inventory**
Hydrogen/H-3 (Tritium)	Remote/Emergency Lighting; Radiotracer	Mound - Inventory**
Iodine/I-125 -131	Seed Implant Therapy; Thyroid Treatment; Medical Imaging	Planned for Sandia - ACRR
Iridium/Ir-192	Industrial Radiography Sources	Idaho - ATR Oak Ridge - HFIR
Iron/Fe-54* -57 -58	Target for Fe-55 (medical isotope); Metallurgy/Solid State Physics Agricultural Biology Solid State Physics	Oak Ridge - Calutrons
Krypton/Kr-78* -86	Optics (standard light sources); Reactor Fuel Tagging; Pulmonary Diagnosis	Mound**

* Separated Stable Isotopes; all others are radionuclides.

** All Mound inventories were shipped to Oak Ridge National Laboratory in fiscal year 1996 for future distribution.

PROMINENTLY SOLD ISOTOPES AND THEIR USES
FISCAL YEAR 1996

<u>ELEMENT/ISOTOPES</u>	<u>IMPORTANT USES</u>	<u>WHERE AVAILABLE</u>
Lead/Pb-204*	Chemical Analyses Target for Pb-205 (used in geology research)	Oak Ridge - Calutrons
Lithium/Li-6*	Physics and Chemistry Research; Neutron Capture Therapy Research	Oak Ridge - Inventory
Lutetium/Lu-176*	Basic Physics Research	Oak Ridge - Calutrons
Magnesium/Mg-28	Physiological Tracer	Brookhaven - BLIP
Molybdenum/Mo-99	General Medical Imaging	Planned for Sandia - ACRR
Nickel/Ni-61* -62	Reactor Targets for radioisotope formation	Oak Ridge - Calutrons
Nickel/Ni-63	Gas Sensing Devices; Metabolic Radiotracer	Idaho - ATR Oak Ridge - HFIR
Palladium/Pd-103	Prostate Cancer Implant Therapy	Oak Ridge - HFIR
Phosphorus/P-32	Leukemia; Bone Disease	Planned for Sandia - ACRR
Rubidium/Rb-87*	Geology; Chemical Analyses; Beta Source	Oak Ridge - Calutrons
Samarium/Sm-152*	Target for Sm-153 Production (used in medical research including bone cancer/ arthritis)	Oak Ridge - Calutrons
Silicon/Si-29*	Geology; Molecular Studies	Oak Ridge - Calutrons
Sodium/Na-22	Neurologic Research	Los Alamos - LANSCE
Strontium/Sr-82 -85 -89	Cardiac Imaging; Diagnosis of Bone Lesions; Hypoparathyroidism Bone Cancer pain relief	Los Alamos - LANSCE Brookhaven - BLIP Los Alamos - LANSCE

* Separated stable isotopes; all others are radionuclides.

PROMINENTLY SOLD ISOTOPES AND THEIR USES
FISCAL YEAR 1996

<u>ELEMENT/ISOTOPES</u>	<u>IMPORTANT USES</u>	<u>WHERE AVAILABLE</u>
Strontium/Sr-84* -88	Geology; Reactor Targets for Sr-85 Reactor Targets for Sr-89 (used in bone cancer therapy and labeling of monoclonal antibodies)	Oak Ridge - Calutrons
Thallium/Tl-203*	Targets for Tl-201 Production in Accelerators (Tl-201 used in cardiac imaging)	Oak Ridge - Calutrons
Uranium/U-234	Neutron Sensing; Control Instrumentation	Oak Ridge - Inventory
Xenon/Xe-124* -126	Reactor Fuel Tagging; Targets for radioiodine production in reactors	Mound - Inventory***
Xenon/Xe-127** -133	Neuroimaging; Lung Ventilation Lymphoid Tumor therapy; Lung Imaging	Brookhaven - BLIP Planned for Sandia - ACRR
Yttrium/Y-90	Cancer Therapy	Westinghouse Hanford
Zinc/Zn-66* -68 -70	Reactor Activation Reduction; Targets for Radionuclide Production (e.g., Ga-67, used for soft tumor scanning and diag. of Hodgkin's Disease)	Oak Ridge - Calutrons
Zirconium/Zr-90* -92 -94 -96	Irradiation Targets - Research	Oak Ridge - Calutrons

* Separated stable isotopes; all others are radionuclides.

** Xe-127 not currently scheduled for production.

*** All Mound inventories shipped to Oak Ridge National Laboratory in fiscal year 1996 for future distribution

Independent Auditors' Report on Compliance with Laws and Regulations

Office of Nuclear Energy
United States Department of Energy:

We have audited the financial statements of the United States Department of Energy's (Department) Isotope Production and Distribution Program (Isotope Program, or Program) as of and for the year ended September 30, 1996, and have issued our report thereon dated December 13, 1996.

We conducted our audit in accordance with generally accepted auditing standards; *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin 93-06, *Audit Requirements for Federal Financial Statements*. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

Compliance with laws and regulations applicable to the Isotope Program is the responsibility of Program management. As part of obtaining reasonable assurance about whether the financial statements are free of material misstatement, we tested compliance with laws and regulations that may directly affect the financial statements and certain other laws and regulations designated by OMB and the United States Department of Energy, including: *Public Law 101-101*, which created the Isotope Production and Distribution Program revolving fund; the *Budget and Accounting Procedures Act*; and the *Federal Managers' Financial Integrity Act*. However, the objective of our audit of the financial statements was not to provide an opinion on overall compliance with such laws and regulations. Accordingly, we do not express such an opinion.

As part of our audit, we also obtained an understanding of management's process for evaluating and reporting on internal control and accounting systems as required by the Federal Managers' Financial Integrity Act (FMFIA) and compared the Isotope Program's most recent FMFIA reports with the evaluation we conducted of the Program's internal control structure.

The results of our tests of compliance resulted in no instances of noncompliance required to be reported herein under *Government Auditing Standards* or OMB Bulletin 93-06.

This report is intended for the management of the Isotope Program and the United States Department of Energy. This restriction is not intended to limit the distribution of this report, which is a matter of public record.

KPMG Peat Marwick LLP

December 13, 1996

Independent Auditors' Report on the Internal Control Structure

Office of Nuclear Energy
United States Department of Energy:

We have audited the financial statements of the United States Department of Energy's (Department) Isotope Production and Distribution Program (Isotope Program, or Program) as of and for the year ended September 30, 1996, and have issued our report thereon dated December 13, 1996.

We conducted our audit in accordance with generally accepted auditing standards; *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin 93-06, *Audit Requirements for Federal Financial Statements*. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

The management of the Isotope Program is responsible for establishing and maintaining an internal control structure. In fulfilling this responsibility, estimates and judgments by management are required to assess the expected benefits and related costs of internal control structure policies and procedures. The objectives of an internal control structure are to provide management with reasonable, but not absolute, assurance that transactions, including those relating to obligations and costs, are executed in compliance with applicable laws and regulations that could have a direct and material effect on the financial statements and any other laws and regulations that OMB, Program management, or the Department of Energy have identified as being significant and for which compliance can be objectively measured and evaluated; funds, property, and other assets are safeguarded against loss from unauthorized use or disposition; transactions are executed in accordance with management's authorization and properly recorded and accounted for to permit the preparation of reliable financial reports in accordance with the accounting policies described in note 1 to the financial statements and to maintain accountability over the assets; and data that support reported performance measures are properly recorded and accounted for to permit preparation of reliable and complete performance information. Because of inherent limitations in any internal control structure, errors or irregularities may nevertheless occur and not be detected. Also, projection of any evaluation of the structure to future periods is subject to the risk that procedures may become inadequate because of changes in conditions or that the effectiveness of the design and operation of policies and procedures may deteriorate.

In planning and performing our audit of the financial statements of the Isotope Program for the year ended September 30, 1996, we obtained an understanding of the internal control structure. With respect to the internal control structure, we obtained an understanding of the design of relevant policies and procedures and whether they have been placed in operation, and we assessed control risk in order to determine our auditing procedures for the purpose of expressing our opinion on the financial statements and not to provide an opinion on the internal control structure. Accordingly, we do not express such an opinion.

Our evaluation of the controls for performance information was limited to those controls designed to ensure the existence and completeness of the information. With respect to the performance measure control objective, we obtained an understanding of the relevant internal control structure policies and procedures designed to permit the preparation of reliable and complete performance information, and we assessed control risk.

We noted one matter involving the internal control structure and its operation that we consider to be a reportable condition under standards established by the American Institute of Certified Public Accountants and OMB Bulletin 93-06. Reportable conditions involve matters coming to our attention relating to significant deficiencies in the design or operation of the internal control structure that, in our judgment, could adversely affect the Isotope Program's ability to ensure that the objectives of the internal control structure, as previously defined, are being achieved. The condition that we consider to be a reportable condition is included in Exhibit I of this report.

A material weakness is a reportable condition in which the design or operation of one or more of the specific internal control structure elements does not reduce to a relatively low level the risk that errors or irregularities in amounts that would be material in relation to the financial statements being audited, or material to a performance measure or aggregation of related performance data, may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions.

Our consideration of the internal control structure would not necessarily disclose all matters in the internal control structure that might be reportable conditions and, accordingly, would not necessarily disclose all reportable conditions that are also considered to be material weaknesses as defined above. We noted no matters involving the internal control structure and its operations that we consider to be material weaknesses.

This condition was considered in determining the nature, timing, and extent of the audit tests applied in our audit of the September 30, 1996 financial statements, and does not effect our report dated December 13, 1996 on these financial statements.

We also noted other matters involving the Isotope Program's internal control structure and its operations that we have reported to Program management in a separate letter dated December 13, 1996.

This report is intended for the information of the management of the Isotope Program and the United States Department of Energy. This restriction is not intended to limit distribution of this report, which is a matter of public record.

KPMG Peat Marwick LLP

December 13, 1996

**UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY**

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Reportable Condition

Outstanding Comment from Previous Reports

Billing and Revenue Recognition - BNL

Audit Comment

Our 1994 and 1995 reports described significant delays in recording isotope sales and collecting receivables at BNL. The Chicago Operations Office responded that BNL would be instructed to issue invoices to customers and to record sales in a timely manner.

The Department's standard practice is to bill within five to seven days of shipment. In fiscal year 1996, we identified one sale in excess of \$179,000 that was not billed until 45 days after shipment. Review of the Program's shipments summary report revealed similar delays for many other fiscal year 1996 shipments. These delays result primarily from BNL's policy of only issuing invoices only once a month, regardless of the shipment date. The extended period of time between shipments and billings causes delays in recording sales and collecting accounts receivable.

Audit Recommendation

As stated in our 1995 report, Isotope Program management should instruct BNL to issue invoices to customers and record sales in a timely manner.

Management Response

Concur. Effective October 1, 1996, formal policies and procedures were established and implemented, whereby the BNL Medical Department will bill isotope sales directly. This should ensure timely issuance of invoices and recording of sales.

Peat Marwick LLP

2001 M Street, N.W.
Washington, DC 20036

Office of Nuclear Energy
United States Department of Energy:

We have audited the financial statements of the United States Department of Energy's Isotope Production and Distribution Program (Isotope Program, or Program) as of and for the year ended September 30, 1996, and have issued our report thereon dated December 13, 1996. In planning and performing our audit of the financial statements of the Isotope Program, we considered its internal control structure in order to determine our auditing procedures for the purpose of expressing our opinion on the financial statements and not to provide assurance on internal control.

Reportable conditions are matters coming to our attention that, in our judgment, relate to significant deficiencies in the design or operation of the internal control structure and could adversely affect the Program's ability to record, process, summarize, and report financial data consistent with the assertions of management in the financial statements. Our consideration of the internal control structure would not necessarily disclose all matters in the internal control structure that might be reportable conditions.

We noted one matter involving the internal control structure and its operations that we consider to be a reportable condition under standards established by the American Institute of Certified Public Accountants and OMB Bulletin 93-06. This condition has been discussed with the appropriate members of management, and is presented in our Independent Auditors' Report on the Internal Control Structure, dated December 13, 1996.

This condition was considered in determining the nature, timing, and extent of the audit tests applied in our audit of the Isotope Program's 1996 financial statements, and does not affect our report on those financial statements dated December 13, 1996. We have not considered the internal control structure since the date of our report.

Although not considered to be reportable conditions, we noted certain matters involving the internal control structure and other operational matters that are presented herein for your consideration. Our comments and recommendations, all of which have been discussed with the appropriate members of management, are intended to improve the internal control structure or result in other operating efficiencies and are summarized in Exhibit I.

We would like to take this opportunity to acknowledge the courtesy and assistance extended to us by the management of the Isotope Program and other employees of the Department during the course of our audit.

Member firm of
KPMG Peat Marwick Goertzel

This report is intended for the information and use of the Isotope Program's management, and others within the Office of Nuclear Energy. This restriction is not intended to limit distribution of this report, which is a matter of public record.

KFUG Real. Manwick LTD

December 13, 1996

UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Standard General Ledger Implementation

Audit Comment

Our 1995 letter to management (1995 letter) stated that Office of Management and Budget (OMB) Circular A-127, *Financial Management Systems* (A-127), requires Federal agencies to record financial events throughout their financial management systems by implementing the U. S. Treasury's Standard General Ledger (SGL) account numbers at the transaction level, effective October 1, 1993. To comply with A-127, agencies must prepare financial reports and record transactions in a manner consistent with SGL rules, and should have supporting transaction detail readily available for SGL accounts.

Our 1995 letter further stated that the Department intended to convert Departmental Integrated Standardized Core Accounting System (DISCAS) data fields to utilize Treasury's SGL account numbers, but that the Department was unable to determine when the DISCAS modifications will be completed. Our letter recommended that the Department complete modifications in its federal financial systems to satisfy the SGL requirements as soon as possible.

Management concurred with the finding and recommendations and took action to correct logic and account offset errors and to fully document reporting conversion methods. Management also stated that, while it concurred with the recommendation to implement SGL at the transaction level, implementation could not occur until funding was available. Management further stated that it plans to implement the SGL at the transaction level with the implementation of the new Management Analysis Reporting System (MARS). However, management was unable to determine the date for transaction level implementation.

Management's proposed actions are responsive to the recommendations. While we recognize that funding constraints exist, implementation of the SGL at the transaction level is critical to satisfying both Departmental and Government-wide financial reporting objectives. Management should reconsider funding priorities where necessary to implement the SGL requirement.

Audit Recommendation

No further recommendation is necessary at this time.

Management Response

Consistent with our fiscal year 1995 response, the Department plans to implement the SGL at the transaction level with the implementation of MARS. The MARS development consists of four distinct phases. Phase 3A, currently in progress, includes a crosswalk of MARS accounts to SGL accounts. Phase 3B will include implementation of the SGL at the transaction level and will require significant modifications to DISCAS. Completion of Phase 3B is planned by September 30, 1998.

UNITED STATES DEPARTMENT OF ENERGY
OFFICE OF NUCLEAR ENERGY

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

**Implementation of Statement of Federal Financial Accounting
Standards No. 4, *Managerial Cost Accounting Concepts for the
Federal Government***

Audit Comment

Statement of Federal Financial Accounting Standards No. 4, *Managerial Cost Accounting Concepts for the Federal Government* (Standard 4), effective for fiscal periods beginning after September 30, 1996, requires reporting entities to report the full costs of outputs in financial reports. The full cost of an output produced by a responsibility segment is the sum of: (1) the cost of resources consumed by the segment that directly or indirectly contribute to the output; and (2) the costs of identifiable supporting services provided by other responsibility segments within the reporting entity, and by other reporting entities.

In fiscal year 1996 and previous years, the Program's financial statements only included costs funded through revenues from the sale of isotopes and related services, congressional appropriations and payments received from the isotope support decision unit. As a result, the Isotope Program's fiscal year 1996 financial statements do not include the costs of pensions, retiree medical benefits, and other post-retirement benefits. These benefits are paid through appropriations to the Office of Personnel Management, and the costs of such benefits are not currently allocated to the Department or its programs. In addition, the financial statements currently exclude Departmental administration and other costs allocable to the Program by other entities within the Department such as the Office of the Chief Financial Officer, both at Headquarters and in field offices.

Based on the requirements of Standard 4, Isotope Program management should ensure that the full cost of outputs is properly reflected in the fiscal year 1997 financial statements. Costs funded by other entities should be reported as a financing source.

Audit Recommendations

1. The Office of the Chief Financial Officer should prepare allocations of Departmental administration and other allocable costs to Departmental reporting entities; and
2. Isotope Program management should ensure that the Program's financial statements include all costs allocable to the Program's outputs.

Management Response

The Department of Energy fully intends to comply with Statement of Federal Financial Accounting Standards Number 4. Implementation will be accomplished on a Department-wide level with the Office of the Chief Financial Officer (CFO) taking the lead. Accordingly, the CFO is participating in the Government-wide Cost Accounting Work Group, Full and Inter-Entity Costs Subgroup, whose goal is developing guidelines for the implementation of the Federal Accounting Standards Advisory Board Standards.