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United States Government

Department of Energy

memorandum

DATE: March 27, 1998

REPLY TO
ATTN OF: IG-30

SUBJECT: Isotope Production and Distribution Program's Fiscal Year 1997 Financial Statement Audit (ER-FC-98-03)

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 Program) statements of financial position, and the related statements of operations and changes in net position, and cash flows. The auditors have expressed an unqualified opinion on the 1997 statements.

The 1997 financial statement audit was made under the provisions of the Inspector General Act of 1978 as amended, (5 U.S.C. App. 3), the Government Management Reform Act (31 U.S.C. 3515), and Office of Management and Budget implementing guidance. The auditors' 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' reports on Isotope Program's internal control structure and compliance with laws and regulations disclosed no reportable conditions or instances of noncompliance.

Based on KPMG's unqualified opinion and our review of their audit work, we believe the financial statements fairly present the financial condition and results of operations of Isotope Program for the period under audit.

Phillip L. Holbrook

Acting Deputy Inspector General
for Audit Services

Attachment

cc: Audit Liaison, Office of Nuclear Energy
Team Leader, Audit Liaison Team, CR-2
Manager, Eastern Regional Audit Office, IG-36

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

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Financial Statements

September 30, 1997 and 1996

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

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

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September 30, 1997 and 1996

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U.S. Department of Energy

Isotope Production and Distribution Program

Fiscal Year 1997 Financial Statement

Overview

Introduction

The Department of Energy (DOE or the Department) Isotope Production and Distribution Program (Isotope Program) mission is to serve the national need for a reliable supply of isotope products and services for medicine, industry and research. The program produces and sells hundreds of stable and radioactive isotopes that are widely utilized by domestic and international customers. Isotopes are produced 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 will sell or lease its existing facilities and inventories for commercial purposes.

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 (FY) 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 FY 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. Although the Isotope Program functions as a business, prices set for small-volume, high-cost isotopes that are needed for research purposes may not achieve full-cost recovery. As a result, isotopes produced by the Isotope Program for research and development are priced to provide a reasonable return to the U.S. Government without discouraging their use. Commercial isotopes are sold on a cost-recovery basis. Because of its pricing structure, when selecting isotopes for production, the Isotope Program must constantly balance current isotope demand, market conditions, and societal benefits with its determination to operate at the lowest possible cost to U.S. taxpayers.

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. Industries such as

medical imaging by emission tomography, nondestructive testing, and radiation sterilization depend on the ready availability of isotopes. Isotopes are particularly important tools in medical research, diagnosis, 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 \$7-\$10 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 therefore essential to maintain the effective diagnosis, treatment, and research capabilities of the Nation's health care system.

Figure 1. Applications of DOE Supplied Isotopes

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 must be separated and enriched through electromagnetic separation. While radioactive isotopes (radioisotopes) also occur naturally, many are produced in reactors through neutron absorption followed by radioactive decay. Other radioisotopes are produced in accelerators by bombarding materials with charged atomic particles followed by radioactive decay. In some cases, isotopes are extracted from the waste byproducts of the Department's Weapons Program activities.

Several DOE facilities are equipped for the separation and production processes described above. Radioisotopes produced by the Isotope Program originate at Los Alamos National Laboratory (LANL), Brookhaven National Laboratory (BNL), Pacific Northwest National Laboratory (PNNL), and Oak Ridge National Laboratory (ORNL). Stable isotopes are separated and enriched in ORNL's Electromagnetic Isotope Enrichment Facility (calutrons). The Isotope Program's products and services are sold by the DOE site that produces and/or supplies them. 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.

Program Performance Measures

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 program's efficiency and reliability. Since 1996, the Isotope Program has sought to meet this goal by creating opportunities for private industry to assume control of some or all of its production and distribution activities. The objectives of this privatization initiative are to increase the private sector's role in isotope production and supply, enhance U.S. economic competitiveness, create private sector jobs, and reduce the cost of the DOE isotope production and distribution activities to U.S. taxpayers.

On October 1, 1996, isotope production activities at Idaho National Engineering and Environmental Laboratory (INEEL) were commercialized. This and the commercialization of the Test Reactor Area Hot Cells at INEEL is saving the Isotope Program about \$750,000 to \$1.0 million annually without decreasing service to its customers.

The Isotope Program has identified specific activities that can be privatized. After a thorough evaluation process, three requests for proposals were developed in FY 1997 and were subsequently issued in early FY 1998. A fourth request for proposals will be developed and issued in FY 1998. Contracts for the four proposed activities will be awarded in FY 1998 if acceptable bids are received. In addition, the Isotope Program will continue to identify other activities that have a privatization potential, such as target fabrication for production of other isotopes and molybdenum-99 production and distribution.

Customer Service

The Isotope Program's data bank includes hundreds of customers. A total of 276 customers were serviced in FY 1997, resulting in 1,110 shipments. Since Isotope Program sales are not static, the number of customers served and deliveries made are influenced by a number of external and international factors such as production and processing cycles, demand, and competition. Ten formal customer complaints and four formal compliments were received in FY 1997. Ninety-seven percent of the isotopes ordered from the Isotope Program were delivered to customers on schedule.

Figure 2. Customers Served

Process Development

A highly significant, ongoing Isotope Program initiative is the establishment of a U.S. capability for the production of molybdenum-99. Molybdenum-99 is a precursor of technetium-99, an isotope used in over 36,000 medical procedures each day in the United States alone. At present, there is no domestic source of molybdenum-99, which is essential to the U.S. health care system. Currently, approximately 60 percent of U.S. molybdenum-99 requirements are supplied by a single, aging reactor in Canada.

To ensure a reliable domestic source of supply of this vital isotope, the Department initiated a project to establish a U.S. molybdenum-99 production capability. Sandia National Laboratories' Annular Core Research Reactor (ACRR), Sandia's nearby Hot Cell Facility (HCF), and LANL's Chemistry and Metallurgy Research Facility were chosen to produce the isotope. Initial molybdenum-99 production runs for quality samples were conducted from October through December 1996. In 1997, the Department altered its facility modification plan so that, by the end of FY 1998, the facilities will be able to provide about 70 percent of the U.S. supply on a sustained basis. U.S. Food and Drug Administration approval of the product will be sought in mid-1999. Continuous production of about 5 percent of the U.S. molybdenum-99 demand is planned in late 1999.

Notable FY 1997 accomplishments for the molybdenum-99 project included demonstrating the chosen facilities' ability to produce a quality product. This demonstration fulfilled a commitment made by the Secretary of Energy and produced sample quantities of the product for quality inspection by a major pharmaceutical company. Also, a sample was sent to MDS Nordion, the manufacturer in Ontario, Canada, to ensure the product met their requirements.

In addition, the ACRR and HCF were prepared for the molybdenum-99 production demonstration. Related activities included improvements to the HCF processing zone such as upgrading window shielding and installing new processing equipment; preparation, review, and approval of all procedures and safety evaluations required for target irradiation in the ACRR and processing in the HCF; and development and review of hardware designs for planned modifications to the ACRR. By the end of FY 1997, the ACRR had been modified for continuous production of molybdenum-99.

An ongoing research and process development initiative involves the use of radioisotopes that emit alpha particles. Results from studies at various cancer research institutions suggest that alpha-emitting radioisotopes may be useful in treating certain cancers. The Isotope Program will provide the 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 valuable, alpha-emitting radioisotopes.

In FY 1997, the Isotope Program funded the installation of an electromagnetic isotope separator in the TA-48 Hot Cell at LANL. This device could potentially increase the shelf-life of several isotopes to make them available throughout a greater part of the calendar year. Because of cost and schedule delays as noted in the Supplemental Financial and Management Information (see page 21), the installation will be completed in FY 1998. Another project started in FY 1997 at LANL was the preparation of a Conceptual Design Report for the 100 MeV Isotope Production Facility (IPF). Construction of the proposed new IPF at LANL is critical. Without construction of this facility, isotope production will cease at the laboratory after FY 1999. The cost of the construction project is estimated at \$12 million and the IPF should be ready for routine operation in late summer of 2000.

Marketing

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

site visits and attendance at society exhibitions (such as those conducted by 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 pressures, competition, and customer feedback is also being obtained through independent surveys and studies as well as program management assessments.

Figure 3. Isotope Customers Categories

Financial Performance

Isotope sales projections for FY 1997 were \$11.6 million while actual sales were \$10.9 million. Isotope Program sales since FY 1992 and the sales projection for FY 1998 are shown in Figure 4.

As shown, FY 1997 sales decreased a total of \$5.9 million below total FY 1996 sales. This decrease was due to privatization of some isotopes, the unexpected duration of the High Flux Isotope Reactor outage at ORNL, changes in customer requirements, and newly aggressive foreign competition. Although sales have decreased, costs of sales and services (manufacturing expenses) have decreased but not proportionally. Adjustments to curtail operational costs and staff will be made in FY 1998.

Figure 4. Sales Trends

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 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 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 Inspector General and 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 (Department) Isotope Production and Distribution Program (Isotope Program, or Program) as of September 30, 1997 and 1996, 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 Program management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with generally accepted auditing standards; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 93-06, *Audit Requirements for Federal Financial Statements*, as amended on January 16, 1998. 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.

As described in note 1(d), these financial statements were prepared in conformity with the hierarchy of accounting principles and standards recommended by the Federal Accounting Standards Advisory Board. This hierarchy is a comprehensive basis of accounting other than generally accepted accounting principles.

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, 1997 and 1996, and the results of its operations and changes in net position and its cash flows for the years then ended, in conformity with the basis of accounting described in note 1(d).

As described in notes 1(m) and 12, the Program implemented Statement of Federal Financial Accounting Standards (SFFAS) No. 5, *Accounting for Liabilities of the Federal Government*, effective October 1, 1996, and SFFAS No. 6, *Accounting for Property, Plant, and Equipment*, effective October 1, 1996, respectively.

Our audit was conducted for the purpose of forming an opinion on the basic financial statements taken as a whole. The information 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 Nos. 94-01 and 97-01, *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 express no opinion on it. Performance information included in management's *Overview and Supplemental Financial and Management Information* is addressed in our auditors' report on internal control over financial reporting and performance information in accordance with OMB Bulletin No. 93-06, as amended.

In accordance with *Government Auditing Standards*, we have also issued reports dated February 5, 1998 on our consideration of the Isotope Program's internal control over financial reporting and performance information and on its compliance with laws and regulations.

This report is intended for the information of the Department's Office of Inspector General and Isotope Program management. However, this report is a matter of public record and its distribution is not limited.

KPMG Peat Marwick LLP

February 5, 1998

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

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Statements of Financial Position

September 30, 1997 and 1996

<u>Assets</u>	<u>1997</u>	<u>1996</u>
Entity assets:		
Intragovernmental assets:		
Fund balance with Treasury	\$ 11,760,647	17,868,862
Accounts receivable, net (note 2)	379,816	584,729
	<u>12,140,463</u>	<u>18,453,591</u>
Governmental assets:		
Accounts receivable, net (note 2)	1,369,157	1,749,747
Inventories, net (note 3):		
Radioisotopes	1,725,629	2,084,811
Stable isotopes	6,424,157	4,525,918
Total inventories	<u>8,149,786</u>	<u>6,610,729</u>
Equipment, net (note 4)	1,898,040	1,440,690
Total entity assets	<u>\$ 23,557,446</u>	<u>28,254,757</u>
 <u>Liabilities and Net Position</u>		
Liabilities covered by budgetary resources:		
Intragovernmental liabilities:		
Accrued expenses	659,266	55,042
Liabilities not covered by budgetary resources:		
Intragovernmental liabilities:		
Accrued leave	44,026	89,536
Governmental liabilities:		
Customer advances	70,390	148,595
Total liabilities	<u>773,682</u>	<u>293,173</u>
Net position:		
Balances:		
Invested capital (note 1 (c))	41,618,336	41,618,336
Cumulative results of operations	(18,834,572)	(13,656,752)
Total net position	<u>22,783,764</u>	<u>27,961,584</u>
Commitments and contingencies (notes 8, 9, 10, and 11)		
Total liabilities and net position	<u>\$ 23,557,446</u>	<u>28,254,757</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, 1997 and 1996

	<u>1997</u>	<u>1996</u>
Revenues from sales of goods and services:		
To the public:		
Domestic	\$ 6,497,393	7,076,247
Foreign	3,954,288	8,785,660
Total revenues from sales to the public	10,451,681	15,861,907
Intragovernmental sales of goods and services	432,499	910,023
Total revenues from sales of goods and services	10,884,180	16,771,930
Cost of sales and services: (note 1(l))		
Directly related to production runs	(9,308,112)	(10,540,910)
Other production costs	(4,015,442)	(5,047,132)
Total cost of sales and services	(13,323,554)	(15,588,042)
Gross profit (loss) from sales	(2,439,374)	1,183,888
Other financing sources:		
Payments from the isotope support decision unit (note 1 (c))	12,704,000	24,658,000
Imputed financing - pension benefits to be paid by Office of Personnel Management (Note 1(m))	60,790	-
Total other financing sources	12,764,790	24,658,000
Total revenues and financing sources, less cost of sales and services	10,325,416	25,841,888
Expenses:		
Program expenses:		
Process development (note 5)	10,476,524	11,706,478
Marketing and customer service	1,438,664	2,944,599
Isotope storage and distribution	519,159	1,265,901
General and administrative (note 6)	3,116,234	3,396,405
Total program expenses	15,550,581	19,313,383
Other expenses (credits):		
Depreciation of isotope equipment	148,307	231,273
Provision for doubtful accounts receivable	73,561	1,422
Lower of cost or market inventory adjustment (note 3)	(198,333)	(20,311)
Change in allowance for excessive inventory quantities (note 3)	166,813	(634,128)
Gain on sale of equipment	-	(81,250)
Total other expenses (credits)	190,348	(502,994)
Total expenses	15,740,929	18,810,389
Excess (deficiency) of revenues and financing sources over total expenses before cumulative effect of change in accounting principle	(5,415,513)	7,031,499
Cumulative effect of change in accounting principle (note 12)	(223,385)	-
Excess (deficiency) of revenues and financing sources over total expenses	\$ (5,638,898)	7,031,499

(Continued)

**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, 1997 and 1996

	<u>1997</u>	<u>1996</u>
Net position, beginning balance	\$ 27,961,584	20,221,266
Excess (deficiency) of revenues and financing sources over total expenses	(5,638,898)	7,031,499
Non-operating changes (note 7)	461,078	708,819
Net position, ending balance	<u>\$ 22,783,764</u>	<u>27,961,584</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, 1997 and 1996

	<u>1997</u>	<u>1996</u>
Cash flows from operating activities:		
Excess (deficiency) of revenues and financing sources over total expenses	\$ (5,638,898)	7,031,499
Adjustments to reconcile excess (deficiency) of revenues over total expenses to net cash provided by (used in) operating activities:		
Depreciation of isotope equipment	148,307	231,273
Cumulative effect of change in accounting principle	223,385	-
Provision for doubtful accounts receivable	73,561	1,422
Non-operating changes	461,078	708,819
Gain on sale of equipment	-	(81,250)
(Increase) decrease in operating assets:		
Accounts receivable	511,942	83,502
Inventories, net	(1,539,057)	(2,390,719)
Advances and prepayments	-	2,500
Increase (decrease) in operating liabilities:		
Customer advances	(78,205)	56,605
Accrued expenses	604,224	(53,637)
Accrued leave	(45,510)	10,025
Total adjustments	<u>359,725</u>	<u>(1,431,460)</u>
Net cash provided by (used in) operating activities	(5,279,173)	5,600,039
Cash flows from investing activities		
Purchases of equipment	(829,042)	(989,303)
Proceeds from sale of equipment	-	100,000
Net cash used in investing activities	<u>(829,042)</u>	<u>(889,303)</u>
Net increase (decrease) in cash	(6,108,215)	4,710,736
Fund balance with Treasury, beginning of year	<u>17,868,862</u>	<u>13,158,126</u>
Fund balance with Treasury, end of year	<u>\$ 11,760,647</u>	<u>17,868,862</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, 1997 and 1996

**(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 Nos. 94-01 and 97-01 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 facilities discussed in note 1(b) record Isotope 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. 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 mission is to serve the national need for a reliable supply of isotope products and services for medicine, industry, and research. The Program is a user of Departmental facilities and provides funding through the Department's 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 notes 1(i), 1(n), and 13, the full cost of providing the products and services, including such items as labor, benefits and packaging, is charged to the Program.

(Continued)

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

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

Isotope production and related 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; and Pacific Northwest National Laboratory (PNNL), Richland, Washington. In addition, the Program conducts process development activities 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 conducted at LANL.

(c) Revolving Fund and Direct Appropriations

The fiscal year 1990 Appropriations Act, Public Law 101-101 (1990 Act), established an 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 invested capital derived from the 1990 Act and subsequent appropriations is \$41.6 million as of September 30, 1997. 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 an isotope support decision unit in the Department's energy supply, research, and development appropriation. The isotope support decision unit funds payments to the Isotope Program for the production and processing of those isotopes which, although unprofitable, are in the national interest. The Program received \$12.7 million and \$24.7 million in payments from the isotope support decision unit during fiscal years 1997 and 1996, respectively.

(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 monitor 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 (FASAB).

Form and content requirements included in OMB Bulletin Nos. 94-01 and 97-01, *Form and Content of Agency Financial Statements*.

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

(Continued)

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

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

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.

(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. 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. 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 Departmental 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. Prior to fiscal year 1997, equipment costing more than \$5,000 with an expected life of more than two years was capitalized and depreciated on a straight-line basis over the estimated useful life of the asset. Effective October 1, 1996, the capitalization threshold was increased to \$25,000 (see note 12).

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

ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(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.

(l) Cost of Sales and Services

Costs incurred during production runs are directly assigned to individual products. Other production-related costs include such items as idle capacity and maintenance costs that are not assigned to individual products.

(m) 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% 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 (OPM).

The Isotope Program adopted the provisions of FASAB's Statement of Federal Financial Accounting Standards (SFFAS) No. 5, *Accounting for Liabilities of the Federal Government*, effective October 1, 1996. The provisions of SFFAS No. 5 require an employer entity to recognize an expense for its 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 reported as an imputed financing source, as these costs will ultimately be funded by the OPM. The Program recognized total retirement expense of \$133,545 as of September 30, 1997, and an imputed financing source of \$60,790 to reflect the portion of 1997 retirement expense to be paid by OPM.

(Continued)

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

Notes to Financial Statements

(n) Material Produced by Other Programs

Certain isotopes result as byproducts from production activities of other Departmental programs. The Isotope Program acts as a marketing and distribution agent for one marketable byproduct. In fiscal years 1997 and 1996, the Program recognized revenue of approximately \$1.0 million and \$1.3 million, respectively, from sales of this isotope, for which there was no production cost basis.

(o) 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.

(p) Reclassifications

Certain reclassifications have been made to the 1996 amounts to conform to the 1997 presentation.

(2) Accounts Receivable

Accounts receivable consist of the following at September 30, 1997 and 1996:

		1997	
		Governmental	Intragovernmental
Accounts receivable		\$ 1,443,422	379,816
Less allowance for doubtful accounts		(74,265)	-
		<u>\$ 1,369,157</u>	<u>379,816</u>
		1996	
		Governmental	Intragovernmental
Accounts receivable		\$ 1,752,695	584,729
Less allowance for doubtful accounts		(2,948)	-
		<u>\$ 1,749,747</u>	<u>584,729</u>

(Continued)

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

Notes to Financial Statements

(3) Inventories

Inventories held for sale consist of the following at September 30, 1997 and 1996:

	1997	
	Radioisotopes	Stable Isotopes
Cost	\$ 4,737,905	10,234,375
Less:		
Allowance for excessive inventory quantities	(2,827,850)	(3,445,529)
Adjustment to lower of cost or market value	(184,426)	(364,689)
	<u>\$ 1,725,629</u>	<u>6,424,157</u>
	1996	
	Radioisotopes	Stable Isotopes
Cost	\$ 5,367,519	8,097,224
Less:		
Allowance for excessive inventory quantities	(2,899,949)	(3,206,617)
Adjustment to lower of cost or market value	(382,759)	(364,689)
	<u>\$ 2,084,811</u>	<u>4,525,918</u>

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 1997 and 1996 were \$142,213 and \$151,590, respectively.

Activity in the allowance for excessive inventory quantities for fiscal years 1997 and 1996 is as follows:

	Radioisotopes	Stable Isotopes	Total
Balance, October 1, 1995	\$ 3,591,267	3,149,427	6,740,694
Current year increase (decrease)	(691,318)	57,190	(634,128)
Balance, September 30, 1996	<u>2,899,949</u>	<u>3,206,617</u>	<u>6,106,566</u>
Current year increase (decrease)	(72,099)	238,912	166,813
Balance, September 30, 1997	<u>\$ 2,827,850</u>	<u>3,445,529</u>	<u>6,273,379</u>

(Continued)

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

Notes to Financial Statements

(4) Equipment

Equipment consists of the following at September 30, 1997 and 1996:

	<u>1997</u>	<u>1996</u>
Shipping casks	\$ 628,220	628,220
Production equipment	1,948,304	1,359,731
	<u>2,576,524</u>	<u>1,987,951</u>
Less accumulated depreciation	(678,484)	(547,261)
	<u><u>\$ 1,898,040</u></u>	<u><u>1,440,690</u></u>

(5) Process Development Expenses

The majority of process development expenses relate to the Program's initiative to establish a United States production capability for Molybdenum 99 (Mo-99) and related medical isotopes. Total expenses for this initiative during fiscal years 1997 and 1996 were \$9.1 million and \$10.4 million, respectively. Expenses for other research and development projects amounted to \$1.4 million in fiscal year 1997 and \$1.3 million in fiscal year 1996.

(6) General and Administrative Expenses

General and administrative expenses for the years ended September 30, 1997 and 1996 consist of the following:

	<u>1997</u>	<u>1996</u>
Personal services and benefits	\$ 1,250,487	918,622
Travel and transportation	50,435	49,597
Contractor and other	1,815,312	2,428,186
	<u><u>\$ 3,116,234</u></u>	<u><u>3,396,405</u></u>

(7) 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, 1997 and 1996, consist of:

	<u>1997</u>	<u>1996</u>
Ohio Operations Office	\$ 24,679	101,375
Oak Ridge Operations Office	436,399	606,838
Idaho Operations Office	-	606
	<u><u>\$ 461,078</u></u>	<u><u>708,819</u></u>

(Continued)

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

Notes to Financial Statements

(8) 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, 1997.

(9) Customer Concentration

The Program has one customer that accounted for more than 23% and 28% of total fiscal 1997 and 1996 revenue, respectively. The Program has a long-term contract with this customer that expires on December 31, 1997, but the Department plans to extend the contract to July 1, 1998 and is negotiating the terms of another long-term agreement. As of September 30, 1997, this customer had an outstanding accounts receivable balance of approximately \$167,000.

(10) Environmental Costs

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

(11) Mound and Idaho Divestitures

Isotope Program production facilities were closed at EG&G Mound Applied Technologies (Mound) effective October 1, 1996, and inventories were subsequently transferred to ORNL.

Program activities at the Idaho National Engineering and Environmental Laboratory were transferred to a commercial entity effective October 1, 1996. Certain inventories were retained by the Department, but may be sold by the entity with reimbursement of selling costs by the Department.

(Continued)

UNITED STATES DEPARTMENT OF ENERGY
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ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Notes to Financial Statements

(12) Change in Accounting Principle

The Isotope Program adopted the provisions of FASAB's Statement of Federal Financial Accounting Standards (SFFAS) No. 6, *Accounting for Property, Plant, and Equipment*, effective October 1, 1996.

In conjunction with the implementation of SFFAS No. 6, the Program changed its policy for the capitalization of equipment, increasing the threshold for capitalization from \$5,000 to \$25,000. The new capitalization threshold, which was adopted to reduce administrative costs, has been applied retroactively to equipment acquisitions of prior years. The cumulative effect of this change in accounting principle as of October 1, 1996 is \$223,385, reported as a charge to fiscal year 1997 operations. Implementation of SFFAS No. 6 had no other material accounting or reporting impact on the Program.

(13) Adoption of New Accounting Standard

In fiscal year 1998, the Isotope Program will adopt SFFAS No. 4, *Managerial Cost Accounting Concepts for the Federal Government*, which will require the Program to report the full costs of outputs in its financial statements. The full cost of an output produced by the Program is the sum of: (1) the cost of resources consumed by the Program that directly or indirectly contribute to the Program's outputs; and (2) the costs of identifiable supporting services provided by other Departmental reporting entities. The additional costs resulting from SFFAS No. 4's adoption will be offset in the statement of operations by imputed financing sources. Therefore, adoption of SFFAS No. 4 will have no impact on the Program's financial condition or net position.

Supplemental Financial and Management Information

Introduction

The charter of the Department of Energy (DOE or the Department) 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.

Isotope applications are vital to continued progress in medical research and practice, new industrial processes, and scientific methods. Among the best known of the isotopes 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.

Production Facilities

Oak Ridge National Laboratory (ORNL)

Stable isotopes are separated and enriched in ORNL's Electromagnetic Isotope Enrichment Facility (calutrons). 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 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.

Los Alamos National Laboratory (LANL)

The Isotope Production Facility at LANL produces radioisotopes by using the primary proton beam and neutrons from the beam stop at the Los Alamos Neutron Science Center (LANSCE), a half-mile-long accelerator that delivers medium energy protons. The LANSCE accelerator's unique characteristics 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. Three major products produced at the site are 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.

Brookhaven National Laboratory (BNL)

The Brookhaven Linear Isotope Producer (BLIP) at BNL currently operates about 20 weeks per year and produces strontium-82, germanium-68, copper-67 and other research isotopes. 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.

Program Performance Measures

Privatization

On October 1, 1996, isotope production activities at Idaho National Engineering and Environmental Laboratory (INEEL) were commercialized. This effort was made possible by a commercial-use subcontract from Lockheed Martin Idaho Technologies Company, the management and operating contractor for INEEL, to MAC Isotopes LLC, which now operates INEEL's Test Reactor Area (TRA) Hot Cells for isotope production and sales. MAC Isotopes uses the 250-megawatt Advanced Test Reactor (ATR) at INEEL to produce its products. The two most important isotopes produced at the ATR are iridium-192, used in industrial radiography, and cobalt-60, used in food sterilization and cancer treatment. Commercialization of isotope production activities and the TRA Hot Cells at INEEL has resulted in an annual savings to the Isotope Program of about \$750,000 to \$1.0 million, with no decrease in service to its isotope customers.

On June 1, 1997, the Isotope Program briefed its stakeholders on the current status of its privatization activities at a meeting in San Antonio, Texas. The Department intends to sell certain assets and transfer key functions to allow the private sector to compete for assets or activities that no longer need to be owned or performed by government. Other functions will be outsourced to private contractors. Outsourcing is useful because, in addition to creating price and performance competition, the decision can be easily reversed if government organizations show they can perform an operation better or at less cost than the private sector.

The Isotope Program will continue to advise interested parties and purchasers of specific isotopes on important events (actions taken by the program, *Commerce Business Daily* announcements, etc.).

The Isotope Program and other DOE offices have identified specific activities that can be privatized within one year. After a thorough evaluation process, contracts for privatization of four proposed activities will be awarded in fiscal year (FY) 1998 if qualified bids are received. In addition, the Isotope Program will continue to identify other activities that have a privatization potential such as target fabrication for production of other isotopes and molybdenum-99 production and distribution.

Four activities are underway:

On October 2, 1997, a request for proposals (RFP) was issued for privatization of yttrium-90 production and distribution activities at Pacific Northwest National Laboratory (PNNL). Yttrium-90 is a short-lived radioactive isotope produced from strontium-90, a waste product. Because yttrium-90 emits alpha particles, it is useful in treating cancer, arthritis, and arterial restenosis. A preproposal conference and site tour was held October 22-23, 1997. Four proposals have been received. After a detailed evaluation, contract negotiations will begin in March 1998 with the potential awardee.

On November 7, 1997, a draft RFP was issued for comment on the production, distribution, marketing, billings, and collections of stable isotopes. The business activities and calutron operations at ORNL will be offered for privatization. Enriched stable isotopes are widely used in various applications such as biomedical studies in nutrition and human metabolism and as feed material for the production of radioisotopes.

On December 8, 1997, an RFP was issued for fabrication of targets irradiated in ORNL's HFIR to produce iridium-192. Iridium-192 is used in industrial radiography and medical research related to cancer therapy. Two proposals were received in February 1998. After a detailed

evaluation, contract negotiations will begin in March 1998 with the potential awardee.

An RFP for radioisotope sales, distribution, billing, and collections at multiple locations will be developed and issued in FY 1998.

Program Planning

The Isotope Program is in the process of revising its Five-Year Plan, which is scheduled for issue to the associated sites and field offices in March 1998. This Five-Year Plan will communicate the goals, objectives, strategies, and supporting activities established by management as well as key milestones and performance indicators used to measure the program's success. The plan is updated annually to incorporate site-specific information corresponding to the Isotope Program's established goals and objectives.

Sales Volume Activity

Isotope Program sales projections are dynamic and require frequent modification. Early projections for FY 1997 were approximately \$11.6 million while actual sales totaled \$10.9 million. Total FY 1997 sales decreased by \$5.9 million from total FY 1996 sales (see Figure 4, Sales Trends, page 3). Over twenty-three percent of FY 1997 revenues were received from a Canadian company that purchased isotopes from DOE for resale and distribution to U.S. companies. Twenty customers comprised about 80 percent of Isotope Program sales. In terms of revenue, radioisotopes outsold stable isotopes by a 1.22 to 1 ratio. [A more detailed breakdown of Isotope Program production categories is shown in Figure 5, Isotope Sales By Production Categories.]

Figure 5. Isotope Sales by Production Categories

More than one-third of total sales to the public were made to foreign customers.

To increase sales and reduce unit production costs, high-volume, multiyear contracts with customers will be sought.

Production Development Costs

Molybdenum-99 is a short-lived radioisotope with a 66-hour half-life. It is essential to the production of technetium-99m, an isotope that has applications such as diagnostic studies of the brain, heart, and other organs. Technetium-99m is used in more than 70 percent of all nuclear medicine procedures, which is 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 is the basic motivation for the ongoing initiative to develop a domestic production capability for molybdenum-99 and related isotopes.

To ensure a reliable, U.S. source of supply of this vital isotope, the Department has established a medical isotope production project focused on producing molybdenum-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 process for molybdenum-99 production was demonstrated at these facilities in FY 1996 and improvements to the Hot Cell Facility were made. Molybdenum-99 quality sample production runs began in October 1996 and the product met customer specifications. By the end of 1998, the facilities will be able to provide about 70 percent of the U.S. supply on a sustained basis. U.S. Food and Drug Administration approval of the molybdenum-99 will be sought in mid-1999. Eventually, these facilities could provide 100 percent of the U.S. supply. Total FY 1997 expense for this project was almost \$9.1 million.

LANL experienced a delay in the scheduled installation of an electromagnetic isotope separator in its TA-48 Hot Cell. This device could potentially increase the shelf-life of several isotopes to make them available throughout a greater part of the calendar year, and thereby increase the Isotope Program sales volume and revenues. The construction delay occurred when the Chemistry and Metallurgy Research Facility was placed in operational standdown because of concerns about operating safety. In addition, the cost for the project increased by \$265,000 as a result of an unforeseen personnel change that required training of a new staff member and additional equipment.

Isotopes are produced at LANL when the accelerator is operating to accomplish the primary Department's Office of Defense Programs' missions of the laboratory and on a schedule set by Defense Programs. Defense Programs and the laboratory plan to reconfigure the area immediately in front of the current isotope target station in FY 1999 to

satisfy their future experimentation requirements. After that date, the current target station will be inoperable and isotopes will not be produced at LANL unless the proposed (100 MeV) Isotope Production Facility (IPF) is constructed.

To avoid interruptions in vital isotope supplies and maintain isotope production activities at LANL, the Department has requested funds to relocate the target irradiation station to an area that will not be affected by Defense Programs activities. The new IPF (beam spur) will be constructed at a short spur for 100 MeV beam extraction that was provided in the original beam tunnel design. It will be extended into a small new tunnel and target room where the beam will produce isotopes at least eight months per year unincumbered by other laboratory programs.

In FY 1997, the Department funded the preparation of a Conceptual Design Report (CDR) for the 100 MeV Isotope Production Facility. The CDR was issued on July 25, 1997, and was validated by the Department's Office of Nuclear Energy, Science and Technology on August 15, 1997. The Department's Albuquerque Operations Office performed an independent cost review. LANL is prepared to initiate a more detailed design for this facility as soon as project authorization is received from the Department. Since a more detailed design will be funded from the revolving fund, project authorization is awaiting notification to Congress of the Department's intent. The total project cost is currently estimated at \$12 million. A line item construction request of \$6 million was included in the Department's FY 1999 budget submission to the Office of Management and Budget with the remaining funds planned for the FY 2000 budget request.

Customer Data and Satisfaction

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 276 customers were serviced in FY 1997. The total number of shipments made was 1,110, a decrease of over 44 percent from FY 1996. Of these 1,110 deliveries, 630 were domestic, 367 were foreign, and 113 were intragovernmental.

In FY 1997, more than 97 percent of stable isotope orders were shipped by the promised shipping date and greater than 97 percent of the radioisotopes sold by the Isotope Program were delivered as scheduled. This was an improvement over last year's 93 percent delivery performance that was largely due to inclement weather. Most other delays in FY 1996 involved deliveries of reactor-

produced isotopes and were caused by changes in operating schedules and circumstances related to other programs.

The Isotope Program generally provides high quality products, as evidenced from customer compliments. Of the total amount of 1,110 deliveries, however, the program experienced a few defective products during FY 1997 that are worth noting.

On June 19, 1997, the yttrium-90 production process at PNNL yielded an inferior product. To meet customer requests for the isotope, which is being used in human trial studies of its effect as a treatment for cancer and Hodgkin's disease, two extra production runs were conducted on June 20 and 23 at a cost of about \$20,000. In addition, root-cause analyses were performed to determine the reason for the incident at a cost of \$20,000. Overall, customers have been pleased with the product quality, reliability, and service they have received from PNNL and have expressed their desire for yttrium-90 production to transition smoothly from the Department to the private sector.

Some facilities also experienced problems that resulted in delays in product deliveries and scheduled process improvements. A malfunction of the backup coolant pump at ORNL's High Flux Isotope Reactor (HFIR) caused a two-month delay in restart after a routine summer outage. Consequently, some customer orders were not filled on time, and potential sales opportunities were lost. Loss in sales revenues to the Isotope Program as a result of this incident totaled over \$1.0 million. The direct cost to the program for a lost iridium-192 production target was less than \$2,000.

Financial Performance Measures

Profitability

Total FY 1997 sales decreased \$5.9 million below total FY 1996 sales. This decrease was due to privatization of some isotopes, the unexpected length of the HFIR outage

at ORNL, changes in customer requirements, and newly aggressive foreign competition.

Accounts Receivable Collections

The Isotope Program's net accounts receivable turnover for FY 1997 was 5.3 times, or every 68.9 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 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 1.05 times, based on the average net inventory value during the year.

The inventory turnover to sales for stable isotopes was 0.77 times, based on the average net inventory value during the year. This represents a decrease from the FY 1996 turnover rate of 2.46 times. In the aggregate, it should be noted that isotope inventory analysis is significantly impacted by the wide variety in product types, processes, and lead times.

Isotope Production and Distribution Program

Prominently Sold Isotopes and Their Uses
Fiscal Year 1997

<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*	Research:	Oak Ridge - Calutrons
-43	Nutrition	
-44	Bone Growth	
-46	Nucleosynthesis	
-48	Nuclear Physics	
Californium/Cf-252	Cancer Therapy (especially 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 Production (Such as In-111, Used for Physiological Studies of Soft Tumors)	Oak Ridge - Calutrons
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	Oak Ridge - Inventory
Hydrogen/H-2* (Deuterium)	Isotopic Labeling; Mass Spectrometry Calibration	Oak Ridge - Inventory

* Separated Stable Isotopes; all others are radionuclides.

<u>ELEMENT/ISOTOPES</u>	<u>IMPORTANT USES</u>	<u>WHERE AVAILABLE</u>
Hydrogen/H-3 (Tritium)	Remote/Emergency Lighting; Radiotracer	Oak Ridge - Inventory
Iodine/I-125 -131	Seed Implant Therapy, Thyroid Treatment; Medical Imaging	Planned for Production at Sandia - ACRR
Iridium/Ir-192	Industrial Radiography Sources	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	Oak Ridge - Inventory
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 Production at Sandia - ACRR
Nickel/Ni-61* -62*	Reactor Targets for Radioisotope Formation	Oak Ridge - Calutrons
Nickel/Ni-63	Gas Sensing Devices; Metabolic Radiotracer	Oak Ridge - HFIR
Palladium/Pd-103	Prostate Cancer Implant Therapy	Oak Ridge - HFIR
Phosphorus/P-32	Leukemia; Bone Disease	Planned for Production at 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

* Separated Stable Isotopes; all others are radionuclides.

<u>ELEMENT/ISOTOPES</u>	<u>IMPORTANT USES</u>	<u>WHERE AVAILABLE</u>
Strontium/Sr-82 -85* -89	Cardiac Imaging; Diagnosis of Bone Lesions; Hypoparathyroidism Bone Cancer Pain Relief	Los Alamos - LANSCE Brookhaven - BLIP Los Alamos - LANSCE
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	Oak Ridge - Inventory
Xenon/Xe-127 -133	Neuroimaging; Lung Ventilation Lymphoid Tumor Therapy; Lung Imaging	Brookhaven - BLIP Planned for Production at Sandia - ACRR
Yttrium/Y-90	Cancer Therapy	Richland - Hot Cells
Zinc/Zn-66* -68* -70*	Reactor Activation Reduction; Targets for Radionuclide Production (e.g., Ga-67, Used for Soft Tumor Scanning and Diagnoses 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.

KPMG Peat Marwick LLP

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

Independent Auditors' Report on Compliance with Laws and Regulations

Office of Inspector General and 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, 1997, and have issued our report thereon dated February 5, 1998. Our report refers to the Program's changes in accounting principles with respect to accounting for liabilities and property, plant, and equipment. We conducted our audit in accordance with generally accepted auditing standards; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 93-06, *Audit Requirements for Federal Financial Statements*, as amended on January 16, 1998.

The management of the Isotope Program is responsible for complying with laws and regulations applicable to the Program. As part of obtaining reasonable assurance about whether the Program's financial statements are free of material misstatement, we performed tests of the Program's compliance with certain provisions of laws and regulations, noncompliance with which could have a direct and material effect on the determination of financial statement amounts, and certain other laws and regulations specified in OMB Bulletin No. 93-06, as amended, and designated by the Department, including Public Law 101-101, which created the Isotope Production and Distribution Program revolving fund. However, providing an opinion on compliance with such laws and regulations was not an objective of our audit. Accordingly, we do not express such an opinion.

The results of our tests of compliance with the laws and regulations described in the preceding paragraph disclosed no instances of noncompliance that are required to be reported herein under *Government Auditing Standards* as issued by the Comptroller General of the United States and OMB Bulletin No. 93-06, as amended.

An audit of financial statements conducted in accordance with generally accepted auditing standards; *Government Auditing Standards*, issued by the Comptroller General of the United States; and OMB Bulletin No. 93-06, as amended, is not designed to detect whether the Isotope Program's systems are Year 2000 compliant. Further, we have no responsibility with regard to the Program's efforts to make its systems, or any other systems, such as those of the Program's vendors, service providers, or any other third parties, Year 2000 compliant or provide assurance on whether the Program has addressed or will be able to address all of the affected systems on a timely basis. These are the responsibilities of the Isotope Program's management.

This report is intended for the information of the Department's Office of Inspector General and Isotope Program management. However, this report is a matter of public record and its distribution is not limited.

KDUG Peat Marwick LLP

February 5, 1998

Independent Auditors' Report on Internal Control Over Financial Reporting and Performance Information

Office of Inspector General and 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, 1997, and have issued our report thereon dated February 5, 1998. Our report refers to the Program's changes in accounting principles with respect to accounting for liabilities and property, plant, and equipment. We conducted our audit in accordance with generally accepted auditing standards; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 93-06, *Audit Requirements for Federal Financial Statements*, as amended on January 16, 1998.

The management of the Isotope Program is responsible for establishing and maintaining internal control. In fulfilling this responsibility, estimates and judgments by management are required to assess the expected benefits and related costs of internal control policies and procedures. The objectives of internal control over financial reporting and performance information are to provide management with reasonable, but not absolute, assurance that (1) 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, the Department's Office of Inspector General, or Program management have identified as being significant and for which compliance can be objectively measured and evaluated; (2) funds, property, and other assets are safeguarded against loss from unauthorized use or disposition; (3) transactions are executed in accordance with management's authorization and are properly recorded and accounted for to permit the preparation of reliable financial reports in accordance with the basis of accounting described in note 1 to the financial statements, and to maintain accountability over the assets; and (4) data that support reported performance information are properly recorded and accounted for to permit preparation of reliable and complete performance information.

Because of inherent limitations in internal control, fraud may nevertheless occur and not be detected. Also, projection of any evaluation of internal control 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, we considered the Isotope Program's internal control over financial reporting 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 over financial reporting. Accordingly, we do not express such an opinion. With respect to internal control over financial reporting, we obtained an understanding of the design of relevant policies and procedures, determined if they had been placed in operation, assessed control risk, and performed tests of controls.

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

We noted no matters involving internal control over financial reporting and performance information and its operation that we consider to be reportable conditions under standards established by the American Institute of Certified Public Accountants and OMB Bulletin No. 93-06, as amended. Reportable conditions involve matters coming to our attention relating to significant deficiencies in the design or operation of internal control that, in our judgment, could adversely affect the Isotope Program's ability to ensure that the objectives of internal control, as previously defined are being achieved.

Our consideration of internal control would not necessarily disclose all internal control matters that might be reportable conditions, and accordingly, would not necessarily disclose all reportable conditions that are also considered to be material weaknesses, as defined below. A material weakness is a reportable condition in which the design or operation of one or more internal control components does not reduce to a relatively low level the risk that misstatements, in amounts that would be material in relation to the financial statements being audited, or material to performance information or aggregation of related performance information, may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions. We noted no matters involving internal control over financial reporting and performance information and its operation that we consider to be material weaknesses.

We noted other matters involving internal control and its operation that we have reported to the management of the Isotope Program in a separate letter dated February 5, 1998.

This report is intended for the information of the Department's Office of Inspector General and Isotope Program management. However, this report is a matter of public record and its distribution is not limited.

KDMA Peat Marwick LLP

February 5, 1998

KPMG Peat Marwick LLP

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

Office of Inspector General and 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, 1997, and have issued our report thereon dated February 5, 1998. In planning and performing our audit of the financial statements of the Isotope Program, we considered its internal control over financial reporting and performance information 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 internal control 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 internal control would not necessarily disclose all matters involving internal control and its operation that might be reportable conditions.

We noted no matters involving internal control over financial reporting and performance information and its operation that we consider to be reportable conditions under standards established by the American Institute of Certified Public Accountants and Office of Management and Budget (OMB) Bulletin 93-06, *Audit Requirements for Federal Financial Statements*, as amended on January 16, 1998. We have not considered internal control since the date of our report.

Although not considered to be a reportable condition, we noted one matter involving internal control that is presented herein for your consideration. Our comment and recommendation, which has been discussed with the appropriate members of management, is intended to improve internal control and is summarized as follows:

Cost Accounting - Oak Ridge National Laboratory

Audit Comment

Amounts recorded as cost of sales should reflect the actual cost to produce isotopes sold.

Isotope production activities at EG&G Mound Applied Technologies (Mound) were shut down effective October 1, 1996. Existing inventories of isotopes produced at Mound were subsequently transferred to the Oak Ridge National Laboratory (ORNL). Many of these isotopes have different levels of enrichment, and each enrichment level has a separate cost basis and selling price. Mound recorded isotopes with different enrichment levels separately to account for each individual cost.

Mound transferred the total cost and quantities of inventory to ORNL and provided selling prices by individual isotope. However, because Mound did not provide ORNL a summary of isotope costs and quantities by enrichment level, ORNL does not have the information necessary to record isotopes with different enrichment levels separately. Accordingly, ORNL has combined the cost of individual isotopes with different enrichment levels, and recognizes cost of sales based on the average cost recorded for a particular isotope, regardless of the enrichment level. Therefore, the cost of each sale is misstated to the extent that the actual cost of the isotope sold differs from the average cost for all isotopes whose costs were combined. Further, the combination of costs for different enrichment levels prevents accurate determination of the allowance for excessive inventory quantities and the lower of cost or market adjustment.

Audit Recommendation

The Isotope Program should direct ORNL to segregate the quantities and costs for each enrichment level using either (1) actual historical cost information for individual isotopes transferred from Mound; or (2) an allocation of historical cost based on the selling price for each enrichment level.

Management Response

We concur in principle with the audit recommendation. It should be noted that no future production is planned for the Mound products; hence, only the cost of goods sold for the existing inventory would be impacted. Moreover, the majority of future sales are projected to be Helium-3 which is all the same enrichment level and would not be impacted by the recommended change. In accordance with the recommendation, we will review the current inventory and related enrichment levels of the Mound isotopes and assess the resources required to implement a cost accounting structure which will record the Mound products by enrichment level for each isotope. Given the results of our review, adjustments which are deemed cost beneficial will be made by August 1998.

* * * * *

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 and its contractors during the course of our audit.

This report is intended for the information and use of the Department's Office of Inspector General and Isotope Program 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.

RAMON Deat Marwick LLP

February 5, 1998

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