



U.S. Department of Energy
Office of Inspector General
Office of Audit Services

Audit Report

Management of the Department's Isotope Program

DOE/IG-0709

November 2005




Department of Energy

Washington, DC 20585

November 17, 2005

MEMORANDUM FOR THE SECRETARY

FROM:


Gregory H. Friedman
Inspector General

SUBJECT:

INFORMATION: Audit Report on "Management of the Department's Isotope Program"

BACKGROUND

The Department of Energy's Isotope Program produces and sells radioactive and stable isotopes, and related isotope services. The isotopes are used for research, development, biomedical and industrial applications such as diagnosing and treating cancer, heart disease, and other life-threatening diseases; combating terrorism; and, various environmental applications. This Program is managed by the Office of Nuclear Energy, Science and Technology, and its customer base includes major pharmaceutical companies, research hospitals and universities, other branches of government and private corporations.

Historically, the Department has been responsible for this activity because the market for research and development isotopes has not been commercially viable. Researchers typically request small amounts of isotopes, production techniques are not well established and production costs are high. Declining production levels and recent shifts in mission focus prompted the initiation of this audit to determine whether the Department was effectively and efficiently managing the Isotope Program.

RESULTS OF AUDIT

The audit disclosed that the Department had not always provided researchers with the isotopes needed to conduct planned research. Much of this research was designed to identify breakthroughs in the diagnosis and treatment of various cancers and other life-threatening diseases. Since 1998, independent reviews, many of which were sponsored by the Department, have noted that the Isotope Program did not fully support production of research isotopes and that it had not adequately served the needs of the research community. Our review disclosed similar and continuing problems. For example:

- The Department had not provided researchers from domestic medical centers with isotopes such as Copper-67, which is used to destroy targeted tumors and for lung cancer research; and,



- The Department was unable to respond to about 250 requests for research isotopes from domestic and foreign researchers in FYs 2002 through 2004.

As recognized by independent reviewers, researchers and Program officials, there continues to be a pressing need for research-related isotopes, and the Department is uniquely positioned to address these needs. Nonetheless, the Department:

- Had not adequately addressed recognized production problems during its Isotope Program planning process;
- Adopted pricing and payment policies that made it very difficult, if not impossible, for the research community to purchase the Department's isotopes; and,
- Expended resources on maintaining unused or underutilized production facilities that could have been used to boost or supplement production.

Even though the Department recognized in the 2005 Isotope Program Plan that the current structure of the Program has had a "severe chilling effect on several promising areas of medical research in the United States," it did not take what we considered to be adequate action to address production issues. During the course of our review, a senior Program official indicated that some "temporary fixes" had been implemented to alleviate the impact of current policies on the production and sale of research isotopes. For example, the Isotope Program had been importing targets used for isotope production and working more closely with individuals and institutions such as the Missouri University Research Reactor and the National Institutes of Health to help support isotope production. Nevertheless, the official acknowledged that these actions will neither fix the policy issues nor be effective, long-term solutions.

It should be noted that the constraints on isotope production are tied to a number of fundamental policy decisions, such as the degree to which the Federal Government can or will subsidize the program and decisions regarding dedicating facilities to the production of research isotopes. We made several recommendations designed to help management revitalize the Isotope Program and permit it to better address the research community's needs.

MANAGEMENT REACTION

Management generally concurred with the overall conclusions in the report, but did not agree with all of the recommendations. Management commented that it was aware of the shortage of research isotopes, but felt that the issue was a question of who should financially support production. Where appropriate, we modified our report to address management's concerns. Management's summarized comments, and our responses, have been incorporated in the report. We also included management's comments in their entirety as Appendix 3.

Attachment

cc: Deputy Secretary
Under Secretary for Energy, Science and Environment
Administrator, National Nuclear Security Administration
Chief of Staff
Acting Director, Office of Nuclear Energy, Science and Technology

REPORT ON THE MANAGEMENT OF THE DEPARTMENT'S ISOTOPE PROGRAM

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PRODUCTION OF RESEARCH AND DEVELOPMENT ISOTOPES

Research and Development Isotopes

Dating back to the Atomic Energy Act of 1954, the Department of Energy's (Department) predecessor agency, the Atomic Energy Commission, was authorized to distribute stable and radioactive isotopes at no charge to assist and encourage research on peaceful uses of isotopes involving medical therapy. More recently, the 1990 Energy and Water Appropriations Act consolidated all isotope production and distribution activities under one Department Program and established a revolving fund for the Isotope Program. Congress authorized this fund to, among other things, produce isotopes for use in research and development (R&D). Furthermore, the Isotope Program established an internal goal to "provide a reliable supply of quality products and services based on customers' needs." One of the objectives to support this goal is to "maintain the existing customer base and enhance customer satisfaction."

Our review disclosed that the Department was not adequately supporting production of isotopes needed for R&D and was not always effectively managing the Isotope Program. As noted by researchers, and as bolstered by a number of unfilled requests for research isotopes and ongoing criticisms by independent experts, the Department could better serve the needs of the research community.

Scheduled Isotopes Production

The Department had not provided researchers from domestic medical centers with the isotopes they needed to conduct planned research. Research isotopes were not provided despite commitments to do so as conveyed through the Department's annual production plan. For example, Copper-67, which is used to destroy targeted tumors as cancer therapy and for lung cancer research, was scheduled for production in Fiscal Year (FY) 2004. However, we found that Copper-67 was not actually produced. According to a researcher who expressed an interest in this isotope and whose research was peer-reviewed by the National Cancer Institute, his clinical trials for cancer therapy using Copper-67 were not conducted because the isotope was unavailable. The researcher stated that Copper-67 cannot be obtained elsewhere in the activity and purity level needed. The researcher was told by a

Department official that the new Isotope Production Facility at Los Alamos National Laboratory was supposed to provide this isotope in 2005, but production had been cancelled. In addition to interest by this researcher, there were six other domestic and foreign requests for this isotope during FY 2004 that could not be accommodated.

As another example, the Department did not produce Iron-52 that was scheduled for production in FY 2003. One of this isotope's potential uses is to prepare bone marrow for transplant. A researcher interested in this isotope stated that he could not conduct his proposed research project because the isotope was not available from the Department. We were told that the Brookhaven Linac Isotope Producer at Brookhaven National Laboratory is the only domestic source of Iron-52. While foreign supplies are available, they are not viable because of the isotope's rapid decay.

Unfulfilled Requests

In addition to not providing isotopes that were included in its annual, peer-reviewed production schedule, the Department was unable to respond to about 250 other requests for research isotopes by domestic and foreign researchers during FYs 2002 through 2004. Of the 250 requests, there were:

- 18 requests for Selenium-75. This isotope is a gamma radiography source that can be used for both medical and industrial imaging;
- 13 requests for Technecium-95M, which is a tracer used in high-level radioactive waste R&D; and,
- 7 requests for Iron-55, which is used as a tracer in iron absorption and retention nutrition studies.

In addition to these formal requests, the Isotope Program Director stated that the Program is receiving frequent requests for other research isotopes that it will be unable to fulfill, including Actinium, Lutetium, and Barium. For example, the Department is at its production limit for Actinium, and the Director stated that the Program would sell more of this isotope if more could be produced.

Independent Reviews

As early as 1998, a series of independent reviews, several of which were commissioned by the Department, demonstrated that the Department did not fully support production of research isotopes and had not adequately served the needs of the research community. In spite of recommendations for production-related changes, formal actions to address the situation have not been taken. Examples of these independent reviews include the following:

- A 1998 Expert Panel review, convened at the direction of the Department, found that research isotopes for promising new nuclear medicine products are frequently unavailable or very expensive;
- An April 2000 Nuclear Energy Research Advisory Committee report noted that difficulties experienced by researchers resulting from a lack of isotopes or high costs associated with isotopes in their research are significant and ongoing. The problem was especially apparent in a number of medical research programs that have been terminated, deferred, or seriously delayed by a lack of isotope availability. This review was also commissioned by the Department;
- A May 2002 American Chemical Society position paper criticized the Department's recent payment and pricing changes in the operation of its Isotope Program, citing that these changes will make it virtually impossible for researchers to purchase the Department's isotopes, result in much higher isotope costs, and impede the development of new isotope applications;
- A February 2005 Society of Nuclear Medicine report stated that while the Department had, in the past, played an important role in supplying isotopes to researchers, the Department's production capability had been severely compromised over the years for several reasons, including changes in the operating regime; and,

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- A March 2005 American Nuclear Society report stated that the Department's new pricing and production policies have resulted in a decline of its Isotope Program and a failure to meet its traditional role in isotope production, particularly in supplying isotopes used in research and development.

Program Management Policies and Practices

These issues occurred, in large part, because of problems with Isotope Program management policies and practices. Specifically, the Department:

- Did not adequately address recognized production problems during the Isotope Program planning process;
- Adopted pricing and payment policies that exacerbated production problems and made it very difficult, if not impossible, for the research community to purchase the Department's isotopes; and,
- Expended resources that could have been used to boost or supplement production by maintaining unused or underutilized production facilities.

Planning Practices

The Department's planning practices did not give adequate consideration to meeting the Nation's need for research isotopes. Specifically, although the Department prepares an annual Isotope Program Plan which identifies programmatic issues, it did not develop detailed corrective action plans to address and/or mitigate these problems. For example, the FY 2004 and 2005 Isotope Program Plans acknowledged that the Isotope Program's policies negatively affected the production and sale of research isotopes.

While the Isotope Program has taken some interim steps, it did not suggest or document a course of action to address fundamental policy issues. Furthermore, the Department did not ensure that the Isotope Program developed performance measures to assess its core activity – isotope production. There were no Isotope Program-specific performance measures in the Congressional Budget or the

Department's Performance and Accountability Report for which the Isotope Program was held accountable. While the Isotope Program had a number of internal measures, none measured actual isotope production and/or the Isotope Program's ability to fulfill a certain percentage of requests for research isotopes. Also, there was no clear linkage between these internally-developed performance goals, objectives, and measures, and those contained in the Isotope Program's financial statements and the Congressional budget.

Pricing and Payment Policies

In FY 2003, the Department deviated from its traditional vendor-purchaser policies which included billing at the time of shipment and collection within 30 days. Instead, the Department adopted an advance payment policy, covering the amount of an entire isotope batch, before production could begin. These policy changes occurred in response to Department actions to restrict the Isotope Program's appropriation to maintaining infrastructure, leaving no working capital for isotope production. Once these policies took effect, researchers experienced difficulty purchasing isotopes from the Department. Some researchers could not order isotopes because their universities were prohibited by law from paying in advance. Other researchers could not pay until they received grant funds. The practical effect of the Department's policies was to impair the researchers' ability to purchase the isotopes by forcing them to pay for an entire batch of isotopes, rather than the small amounts they requested.

After the implementation of the batch pricing policy, the sales price of certain research isotopes more than doubled in order to cover the full cost of production. For example, the price of Copper-67 increased from \$480 per unit in FY 2002 to \$1,240 per unit in FY 2003, an increase of nearly 160 percent. The price of Actinium-225, during this same time period, increased from about \$580 to \$1,203 per unit, an increase of over 100 percent. Despite the negative impact these policies had on the research community, the Department did not fully consider alternatives to the advance payment and batch pricing policies such as the pooling of funds (researcher or university associations or consortiums) or waiving the upfront payment.

Maintaining Isotope Production Facilities

The Department is also consuming scarce resources that could be dedicated to research isotope production by maintaining unused or underutilized facilities. Specifically:

- The Annular Core Research Reactor and hot cell facility at Sandia National Laboratories were modified from 1995 to 1999 at a budgeted cost of about \$40 million, but have never been used by the Isotope Program. However, the Isotope Program continues to maintain them at a cost of about \$1.8 million per year.
- The Calutrons at Oak Ridge National Laboratory have not been used since 1998, over seven years. According to the Oak Ridge Isotope Program Manager, the standing order within Nuclear Energy is that the over fifty-year old Calutrons will never operate again. Furthermore, despite an Office of Inspector General audit recommendation in November 2002, the Isotope Program had not formally assessed alternatives to the Calutrons and continued to maintain them at a cost of about \$1.4 million annually.
- The Isotope Production Facility (IPF) has not been fully utilized since it was commissioned and approved to start operations in October 2003. The IPF, which was constructed, in part, to support production of medical and research isotopes, has only been able to make three of the ten isotopes planned for the first production run because the Department did not develop the necessary targets. Furthermore, the IPF is dependent on the operation of the Los Alamos Neutron Science Center (LANSCE) that, according to our report, *The Los Alamos Neutron Science Center* (DOE/IG-0666, November 2004), is becoming unreliable and may not be capable of running effectively in the future. The Headquarters Isotope Program Director indicated that LANSCE will most likely be shut down in FY 2008, and when this occurs, the IPF will no longer be a viable production facility. The Program spends about \$1.7 million annually to maintain the IPF,

and plans to conduct target development work in FY 2005 and beyond to produce additional isotopes.

Officials from Headquarters and all three isotope production sites agree that the current Isotope Program policies have suppressed orders for research isotopes. Specifically, officials acknowledged that recent price increases have made isotopes unaffordable for many researchers. Furthermore, officials also agreed that many researchers are unable to pay for isotopes in advance as currently required. As such, many universities and researchers no longer purchase isotopes from the Department. In addition to direct acknowledgement by Isotope Program officials, the Department's 2005 Isotope Program Plan recognized that the Isotope Program is unable to meet the needs of the medical community for short-lived isotopes, and that the current structure of the Isotope Program has had a "severe chilling effect on several promising areas of medical research in the United States."

Impacts on Research

The audit disclosed that the Department is not providing the needed research isotopes that may lead to future breakthroughs in the diagnosis and treatment of various cancers and other life-threatening diseases. This concern was confirmed by a number of independent research entities and, in reality, by the Department's own analysis.

According to the FY 2005 Isotope Program Plan, if the Department could produce a reliable supply of certain isotopes, there would be immediate use for them in medical research with some moving to clinical trials and widespread application. However, in light of the potential, future shutdown of its newest accelerator facility, the Department's difficulties in producing a reliable supply of medical and research isotopes are likely to continue, or worsen, if action is not taken. Further exacerbating this problem, the National Cancer Institute and the Society of Nuclear Medicine expect there to be a dramatic increase in the use of medical isotopes by the research community for a broad range of efforts. The Department also continues to expend scarce resources maintaining production facilities that may no longer be needed to meet the programmatic mission. As much as \$4.9 million of these funds could be better utilized to subsidize research isotope production or to waive the advance payment policy.

**Program Sponsored
Corrective Actions**

To their credit, the Headquarters Isotope Program Director indicated that some "temporary fixes" have been implemented to alleviate the negative impacts that current policies have had on the production and sale of research isotopes. For example, the Isotope Program has been importing isotope targets from foreign sources and working more closely with individuals from the Missouri University Research Reactor and the National Institutes of Health to help support isotope production. However, the Director acknowledged that these actions will neither fix the policy issues nor be effective, long-term solutions.

RECOMMENDATIONS

We recommend that the Acting Director, Office of Nuclear Energy, Science and Technology:

1. Ensure that processes are in place to address and/or mitigate issues identified during the Isotope Program planning process;
2. Re-evaluate the advance payment and batch pricing policies to consider the impact on the research community and on isotope sales;
3. Establish quantifiable performance measures for isotope production; and,
4. Determine whether the Isotope Program's remaining infrastructure has a viable mission with the Department and make plans to:
 - Maintain, upgrade, or acquire facilities that are essential to the programmatic missions; or,
 - Shut down facilities that are deemed to no longer be needed.

**MANAGEMENT AND
AUDITOR COMMENTS**

The Acting Director, Office of Nuclear Energy, Science and Technology, generally concurred with the overall conclusions in the report. Management agreed with recommendation 2 to reevaluate its advance payment and batch pricing policies and recommendation 5 to continually assess its infrastructure, but disagreed with the other recommendations. To further discuss management's concerns, we met with the Isotope Program officials on October 12, 2005. Their specific comments related to their concerns, followed by our responses, are detailed below.

Management Comment: Management partially agreed with recommendation 1 to ensure that processes are in place to address and/or mitigate issues identified during the Isotope Program planning process. Specifically, management commented that it was aware of the shortage of research isotopes, but did not believe the issue was simply planning processes, but also a question of who should financially support the production of research isotopes. Management emphasized that it was working to establish a financial agreement with the National Institutes of Health to support isotope production and hoped it could establish similar agreements with other agencies. Management added that the issue of isotope availability would be addressed by the National Academy of Sciences in a study planned for FY 2006. During our subsequent discussion, management agreed planning processes are important, but felt that the Isotope Program already has adequate processes in place. Management stated that the more appropriate recommendation would be to re-evaluate the Isotope Program's current policies.

Auditor Comment: We are encouraged by management's actions to address and/or mitigate issues that affect isotope production. We acknowledge that management is aware of problems facing the Isotope Program, such as policy issues, and has taken interim steps to resolve them including working with the National Institutes of Health. However, we did not find the Isotope Program's planning processes to be adequate. For example, management could not demonstrate how its planning process addressed known issues or when corrective steps would be completed through specific action plans.

Management Comment: Management disagreed with recommendation 3 to establish quantifiable performance

measures for isotope production. Management believed that appropriate production performance measures were already in place. As examples, management quoted current measures to ensure production schedules are met 90 percent of the time and to limit rejected and reworked products to 5 percent of the production output.

Auditor Comment: We agree that the Isotope Program has a number of internal measures that address specific production attributes at the site-level. However, the Isotope Program does not have an overall, program-level performance measure that evaluates its success at serving the needs of the research community that is clearly linked to its financial performance and budget request.

Management Comment: Management stated that they agreed with recommendation 4 to discontinue target development efforts at the Isotope Production Facility (IPF) but, in subsequent discussions, indicated that they did not plan to discontinue this effort. Management explained that the IPF targets could be used in the Brookhaven Linac Isotope Producer if LANSCE was shut down and would be available for the IPF if the shutdown did not occur. In the October 12, 2005, meeting, management told us that in July 2005, the Isotope Program decided to re-engineer the target holders at Brookhaven Linac Isotope Producer to accept the new targets being developed for the IPF. The benefit to BLIP is that the new targets achieve higher isotope yields.

Auditor Comment: Given this new development, we have deleted this recommendation from our report.

Management comments are included in their entirety as Appendix 3.

Appendix 1

OBJECTIVE	To determine whether the Department is effectively and efficiently managing the Isotope Program.
SCOPE	We conducted the audit from October 2004 to November 2005 at Department of Energy Headquarters; Oak Ridge National Laboratory (Oak Ridge) in Oak Ridge, TN; Brookhaven National Laboratory (Brookhaven) in Upton, NY; and Los Alamos National Laboratory (Los Alamos) in Los Alamos, NM.
METHODOLOGY	<p>To accomplish the audit objective, we:</p> <ul style="list-style-type: none">• Discussed management of the Isotope Program with officials from Headquarters, Oak Ridge, Brookhaven, and Los Alamos;• Obtained information from the Isotope Reference Information System with assistance from Isotope Business Office officials, to determine the number of unfilled requests for research isotopes;• Contacted researchers from domestic medical centers who were interested in purchasing isotopes from the Department between FY 2003 and 2004;• Reviewed the Isotope Program's financial statements and other documentation to determine the uses of the most frequently unfilled research isotope requests;• Reviewed prior Office of Inspector General, Government Accountability Office, and other independent reviews concerning the Department's Isotope Program;• Reviewed performance related information, including the FYs 2002 through 2004 Congressional Budgets and Performance and Accountability Reports, to determine compliance with the <i>Government Performance and Results Act of 1993</i>;

Appendix 1 (continued)

- Reviewed applicable Federal regulations, Departmental Orders, and Isotope Program policies, procedures, and planning documents; and,
- Analyzed isotope sales prices during FYs 2002 through 2004.

The audit was performed in accordance with generally accepted Government auditing standards for performance audits and included tests of internal controls and compliance with laws and regulations to the extent necessary to satisfy the audit objective. Accordingly, the audit included reviews of Department and regulatory policies, procedures, and performance measures related to management of the Department's Isotope Program. We assessed performance measures in accordance with the *Government Performance and Results Act of 1993* and concluded that the Isotope Program did not develop performance measures covering its core activity of isotope production, as noted in the report. Because our review was limited, it would not necessarily have disclosed all internal control deficiencies that may have existed at the time of our audit. Since computer-processed data was not the primary support to meet our objective, we performed a limited assessment of data reliability.

The exit conference was held with management on November 1, 2005.

PRIOR REPORTS

Office of Inspector General Reports

- *The Los Alamos Neutron Science Center* (DOE/IG-0666, November 2004). This audit concluded that the ability of the Los Alamos Neutron Science Center (LANSCE) to provide needed research capabilities in the future is uncertain. Increasing reliability problems, coupled with the lack of a long-term plan detailing funding and mission priorities, increased the risk that LANSCE may not be capable of operating effectively in the future. These issues occurred because the National Nuclear Security Administration and the Department's Executive Council have yet to complete the analysis necessary to determine whether the facility has a viable future mission.
- *Calutron Isotope Production Capabilities* (DOE/IG-0574, November 2002). This audit concluded that the Department may not be able to ensure the availability of a full range of stable isotopes if the calutrons were dismantled. Despite the assertions by management that the calutrons were no longer needed because alternative sources were available, the audit disclosed that current inventories of some stable isotopes are insufficient to cover future needs; and, no proven domestic alternative capabilities are currently available to replace the calutrons. Furthermore, the Department's strategy included reliance on isotopes supplied by Russia. This strategy carries with it a number of risks which need to be carefully considered in the decision-making process. Therefore, the audit recommended that dismantlement of the equipment be suspended until a reliable and fully demonstrated alternative source of stable isotopes is obtained.

Government Accountability Office Reports

- *Nuclear Science: DOE's Self-Supporting Isotope Program is Experiencing Problems* (GAO/RCED-92-122FS, June 1992). This audit concluded that the Department is experiencing difficulties in operating its isotope sales program on a self-supporting basis. For example, since 1990, the Isotope Program's operating costs have exceeded revenues. Foreign competition and high operating costs have been the primary factors discouraging the Isotope Program's self-sufficient operation. United States isotope users are concerned that the Department's commitment to operating the Program on a self-sufficient basis may limit the domestic availability of certain isotopes if they cannot be produced cost-effectively.

Other Reports

External committees, societies, and expert panels have conducted numerous reviews of the Department's Isotope Program. Below is a sampling of such reviews from the past several years:

Appendix 2 (continued)

- *The US National Isotope Program: Current Status and Strategy for Future Success* (American Nuclear Society, March 2005). Overall, this report found that the United States' isotope program is in a state of crisis, and immediate action is needed to address the major program issues. The issues specifically related to the Department include: (1) research and development (R&D) isotopes are not available at reasonable prices due to declining resources and policy changes; (2) elimination of R&D funding is impacting development of future isotope applications; and, (3) leadership is needed to reverse the decline of the Isotope Program.
- *National Radionuclide Production Enhancement (NRPE) Program: Meeting Our Nation's Need for Radionuclides* (Society of Nuclear Medicine, February 2005). The review found that new radioisotopes for diagnostic and therapeutic uses are not being developed as the national radioisotope infrastructure is chronically under-funded at the Department. New and innovative nuclear medicine treatments will require reliable supplies of domestic radionuclides. However, the majority of radionuclides used in daily applications today are imported on a daily basis, and those required for innovative research are either available sporadically and only in limited quantities or not at all. In response to these challenges, the task force proposed that Congress should realign current radionuclide resources to create an NRPE Program to improve the production of radionuclides in the United States.
- *The Nuclear Chemistry and Technology Division of the American Chemical Society Urges the Maintenance of a Healthy Isotope Program at DOE* (American Chemical Society, May 2002). This position paper stated that two planned changes to the Department's Isotope Program will jeopardize the future development of radionuclides in nuclear and biomedical research. The first change is to discontinue the funding of the Advanced Nuclear Medicine Initiative which supported peer-reviewed research in nuclear medicine. The second change discussed was the Department's plan to require advance payments for development and production of radionuclides. The position paper stated that it will be extremely difficult, if not impossible, for researchers to pay in advance because they typically cannot commit to cash outlays until grants are issued and the money received. If operated as proposed, this paper stated that important research would come to an end and suggested that the advance payment provision be rescinded.
- *Final Report: Nuclear Energy Research Advisory Committee, Subcommittee for Isotope Research & Production Planning* (April 2000). Overall, the review found that recent levels of Federal appropriations have not permitted the Department's isotope supply to keep pace with the changing needs of the research community, and the limited availability of specific radionuclides is a constraint on the progress of research.

Appendix 2 (continued)

- *The Future of Stable Isotope Production in the United States* (JUPITER Corporation, April 15, 1999). This study concluded that small isotope separators using electromagnetic, plasma separation and AVLIS technologies will play a role in providing the future United States stable isotope production capability. Together, these three technologies have the potential to exceed the production capabilities of the Department's Calutrons at substantially reduced costs.
- *Forecast Future Demand for Medical Isotopes* (Expert Panel Review, September 25-26, 1998). The Expert Panel concluded that the Department and the National Institutes of Health must develop the capability to produce a diverse supply of radioisotopes for medical use in quantities sufficient to support research and clinical activities. Such a capability would prevent a shortage of isotopes, reduce American dependence on foreign radionuclide sources, and stimulate biomedical research. The Expert Panel recommended that the United States Government build this capability around either a reactor, an accelerator, or a combination of both technologies as long as isotopes for clinical and research applications can be supplied reliably, with diversity in adequate quantity and quality.

United States Government

Department of Energy

memorandum

DATE: September 28, 2005
REPLY TO:
ATTN OF: NE-40
SUBJECT: Draft Report on *Management of the Department's Isotope Program*
TO: Rickey R. Hass, Assistant Inspector General for Financial, Technology, and Corporate Audits, IG-34

This memorandum provides our comments on the subject draft report.

Generally, we agree with the overall conclusion of this report. The attached "Management Reaction" comments state our current and planned actions that address the report recommendations. However, contrary to the recommendation on performance measures, we believe that the Isotope Programs has effective and sufficient production performance measures in place; the attachment states our position. General and editorial comments are also attached.

If you have any questions, please call John Pantaleo of my staff at 301-903-2525.



R. Shane Johnson, Acting Director
Office of Nuclear Energy, Science
and Technology

Attachment

cc: Team Leader, Audit Liaison, ME-100
Audit Liaison, NE-10

Appendix 3 (continued)

Management Reaction to Recommendations

Office of the Inspector General Draft Audit Report IG-A05-FF-008

Management of the Department's Isotope Program

1. Ensure that processes are in place to address and/or mitigate issues identified during the Isotope Program planning process.

Management partially agrees with this recommendation. Office of Nuclear Energy, Science and Technology (NE) management is acutely aware of the research isotope availability shortage. The issue is who should financially support the production of research isotopes. For about two years, NE management has been working with the National Institutes of Health (NIH), the primary sponsor of most isotope-based medical research in the United States, to establish a new financial interagency agreement between NIH and the Department of Energy (DOE) to enable NIH to support the expanding need for medical research. We believe this type of agreement is achievable and equitable. Moreover, similar agreements could also be established with other Government agencies that purchase isotope products such as Homeland Security and the Environmental Protection Agency (EPA). For example, EPA purchases arsenic-73 used in research as a biomedical tracer for arsenic uptake and retention. This issue will be included in a planned fiscal year 2006 study sponsored by NIH and DOE to be conducted by the National Academy of Sciences to address the "State of Nuclear Medicine." Isotope availability will be part of this study.

2. Reevaluate the advance payment and batch pricing policies to consider the impact on the research community and on isotope sales.

Concur. Management will reevaluate the advance payment and batch pricing policies to consider the impact on the research community and public.

3. Establish quantifiable performance measures for isotope production.

Management does not concur. Quantifiable performance measures for isotope production are in place and are used to assess annual progress in meeting program goals. They are included in the Isotope Program Plan and are part of the program's annual financial statements. For example, two of several performance measures are 1) meet production schedules within ten percent variance and 2) track defective products rejected or campaigns reworked and keep spoiled units to no more than five percent of the total production output by each driver product. The current measures are appropriate.

4. Given plans to shut down the Los Alamos Neutron Science Center (LANSCE) facility, discontinue all future target development efforts related to the Isotope Production Facility (IPF).

Management concurs. However, since the targets that are being developed and fabricated will be interchangeable between the IPF at the Los Alamos National Laboratory (LANL) and the Brookhaven Linac Isotope Producer at Brookhaven

National Laboratory, the program will continue this activity. In the event that LANSCE remains operational, targets will be available for production at the IPF.

5. Determine whether the Isotope Program's remaining infrastructure has a viable mission with the Department and make plans to:
 - Maintain, upgrade, or acquire facilities that are essential to the programmatic missions; or
 - Shut down facilities that are deemed to no longer be needed.

Management concurs and continually assesses infrastructure needs. The annual planning process has resulted in the reduction of seven isotope producing sites to three. This was achieved by consolidation, such as moving all Mound isotope activities to Oak Ridge National Laboratory, and privatization/commercialization of isotope activities such as those at Pacific Northwest National Laboratory. NE management has notified the National Nuclear Security Administration (NNSA) of its intention to shut down the Annular Core Research Reactor (ACRR) unless NNSA is willing to resume ownership of the reactor.

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