DOE Commercializes Idaho Hot-Cell Facility

Responding to calls from Congress and industry to privatize its National Lab facilities, the Department of Energy (DOE) last month signed a landmark contract to lease a hot-cell facility to a fledgling isotope production company. The company will pay for all operating and production costs in return for the freedom to set prices and retain all profits. "Private companies can produce isotopes more efficiently and effectively than the government can," said Owen W. Lowe, associate director for Isotope Production and Distribution for the DOE. "This initiative will reduce the burden to the taxpayer and perhaps provide a price break to customers."

The contract was the culmination of a process begun in December, 1995 when the DOE published a notice in the Federal Register asking companies who were interested in privatizing any of the facilities in its Isotope Production and Distribution Program to submit rough proposals. "We received 30 responses varying from schemes to take over the entire [isotope] program to focused plans involving a part of one facility," said Lowe. Upon reviewing the submissions, the DOE asked for more formal proposals from some companies including Management Analysis Company (MAC) Isotopes, which was granted a five-year contract with a three-year option to extend to run the hot-cell facility at Idaho National Engineering Laboratory on September 30.

Radiopharmaceutical manufacturers had been urging the DOE for years to privatize its isotope production facilities, so that the inflated prices for DOE's radioisotopes could be lowered to market value. The pressure was increased in January 1995 when a panel of corporate executives, called the Galvin Commission, issued a harsh report criticizing the inefficiency of DOE facilities. The Isotope Program's recent privatization initiative "is consistent with the recommendations of the Galvin report," said Lowe. The report recommended overhauling the National Labs and running them like private corporations.

Companies, both inside and outside the nuclear medicine industry, submitted proposals in such areas as: sales and distribution of isotope products and services, target fabrication, production of specific isotopes and packaging of isotopes in a unique form. Lowe would not name the specific isotopes under consideration for privatization, citing companies' requests for confidentiality until the formal competition process takes place, and contracts are negotiated and signed.

A MAC Isotopes employee assays ^{192}Ir pellets at the Idaho National Engineering Lab hot-cell facility. The pellets will be sold commercially for brachytherapy use.

First Signed Contract

As of presstime, the DOE had signed only one contract from the proposals submitted. MAC Isotopes, a start-up isotope production firm in Idaho Falls, signed a lease for the hot cell facility at the Idaho Lab and will maintain the costs of the building and equipment. The company will use the hot cells and reactor to produce isotopes which it will then sell privately to customers.

MAC Isotopes began producing its first isotope, ^{192}Ir, in the facility on October 1 and is currently the only commercial supplier of radioisotopes in the United States according to Steve Laflin, the general manager of MAC Isotopes. The start-up company is owned by its 10 employees, who previously worked at Lockheed Martin, the defense contractor that runs the Idaho Lab for the DOE. So far, it has a firm commitment to sell to two radiopharmaceutical manufacturers, Amersham Healthcare and CISbio, and has a collaboration agreement with the University of Missouri, said Laflin.

Under the contract negotiated with the DOE, the company has the exclusive rights to isotope production in the Idaho reactor and test reactor as well as the hot cells. What is more, it has the freedom to set the prices for the isotopes it sells. "I expect the prices will go down to be competitive with the Russian supply on the market," said Laflin. He said ^{192}Ir, a brachytherapy source, will be priced at $2.85/curie—about 15% to 18% lower than the DOE's price.

Laflin pointed out that this system is distinctly different from a privatization in which companies

DOE Isotope Production and Distribution Program
Prominently Sold Medical and Research Isotopes and Their Uses
Fiscal Year 1995

Element/Isotopes	Important Uses	Where Available
Aluminum (^{26}Al)	Research: Alzheimer's disease; Acid rain	Los Alamos-LANSCE
Calcium (^{42}Ca*) -43 -44 -46 -48	Research: Nutrition Bone growth Nucleosynthesis Nuclear physics	Oak Ridge-Calutrons
Californium (^{252}Cf)	Cancer therapy (esp. ovarium/cervical cancer)	Oak Ridge-HFIR
Cadmium (^{109}Cd)	X-ray fluoreacence instrument calibration; Silver (^{109m}Ag) generation (for short-time medical imaging)	Los Alamos-LANSCE
Cadmium (^{112}Cd*)	Accelerator targets for medical radioisotope prod. (such as ^{111}In used for physiological studies of soft tumors)	Oak Ridge-Calutrons
Cobalt (^{60}Co)	Radiation sources; Cancer teletherapy	Idaho-ATR
Copper (^{67}Cu)	Antibody labeling for cancer therapy and imaging	Los Alamos-LANSCE Brookhaven-BLIP
Dysprosium (^{163}Dy*)	Accelerator research target-neutrino generation	Oak Ridge-Calutrons
Gallium (^{69}Ga*)	Needed in focused ion beam devices for research	Oak Ridge-Calutrons
Germanium (^{68}Ge)	Calibration sources for PET equipment; antibody labeling	Los Alamos-LANSCE Brookhaven-BLIP
Hydrogen (^{2}H*) (Deuterium)	Isotopic labeling; mass spectrometry calibration	Mound-Inventory
Iodine (^{125}I†) -131†	Seed implant therapy; Thyroid treatment; Medical imaging	Sandia-ACRR
Iridium (^{192}Ir)	Industrial radiography sources	Idaho-ATR Oak Ridge-HFIR
Iron (^{54}Fe*) -57 -58	Target for ^{55}Fe (medical isotope); Metallurgy/solid state physics Agricultural biology Solid state physics	Oak Ridge-Calutrons
Krypton (^{78}Kr*) -86	 Pulmonary diagnosis	Mound

are paid to run the lab facilities but must keep government price controls and turn over any profits to the DOE. He emphasized that MAC Isotopes is "getting no government subsidization" specifically because the company wants the freedom to set prices and reinvest profits.

With lower overhead costs, private companies can produce, package and distribute radioisotopes for a fraction of the cost that the government incurs to perform the same job. "The whole point of this [privatization] exercise is to reduce the cost of operations to the taxpayer," said Lowe.

Taking the operation of the Idaho hot cell facility out of the DOE's hands will save U.S. taxpayers about $2 million per year, according to Laflin.

Industry Takes "Wait and See" Approach

Although the DOE's efforts towards privatizing

Element/Isotopes	Important Uses	Where Available
Lead (^{204}Pb*)	Chemical analyses target for ^{205}Pb (used in geology research)	Oak Ridge-Calutrons
Lithium (^{6}Li*)	Physics and chemistry research; Neutron capture therapy research	Oak Ridge-Inventory
Lutetium (^{176}Lu*)	Basic physics research	Oak Ridge-Calutrons
Magnesium (^{28}Mg)	Physiological tracer	Brookhaven-BLIP
Molybdenum (^{99}Mo†)	General medical imaging	Sandia-ACRR
Palladium (^{103}Pd)	Prostate cancer implant therapy	Oak Ridge-HFIR
Phosphorus (^{32}P†)	Leukemia; bone disease	Sandia-ACRR
Rubidium (^{87}Rb*)	Geology; chemical analyses; beta source	Oak Ridge-Calutrons
Samarium (^{152}Sm*)	Target for ^{153}Sm production (used in medical research including bone cancer/arthritis	Oak Ridge-Calutrons
Silicon (^{29}Si*)	Geology; molecular studies	Oak Ridge-Calutrons
Sodium (^{22}Na)	Neurologic research	Los Alamos-LANSCE
Strontium (^{82}Sr) -85 -89	Cardiac imaging; diagnosis of bone lesions; Hypoparathyroidism Bone cancer pain relief	Los Alamos-LANSCE Brookhaven-BLIP Los Alamos-LANSCE DOE reactor site-planned
Strontium (^{84}Sr*) -88	Geology; reactor targets for ^{85}Sr reactor targets for ^{89}Sr (used in bone cancer therapy and labeling of monoclonal antibodies)	Oak Ridge-Calutrons
Thallium (^{203}Tl*)	Targets for ^{201}Tl production in accelerators (^{201}Tl used in cardiac imaging)	Oak Ridge-Calutrons
Xenon (^{127}Xe‡) -133†	Neuroimaging; lung ventilation lymphoid tumor therapy; lung Imaging	Brookhaven-BLIP Sandia-ACRR
Yttrium (^{90}Y)	Cancer therapy	Westinghouse Hamford
Zinc (^{66}Zn*) -68 -70	Targets for radionuclide production (e.g., ^{67}Ga, used for soft tumor scanning and diag. of Hodgkin's disease	Oak Ridge-Calutrons
Zirconium (^{90}Zr*) -92 -94 -96	Irradiation targets-research	Oak Ridge-Calutrons

*Separated stable isotopes; all others are radionuclides.
†First samples planned in 1996.
‡^{127}Xe not currently scheduled for production.
Source: Department of Energy

isotope production sound great in theory, they may not pan out as expected in practice. "This has been a little bit of a rocky road because the government has never done a commercialization," Laflin admitted.

Indeed, nuclear medicine industry leaders see MAC Isotopes as a litmus test that will indicate whether the DOE's plans will pass or fail. "We are somewhat hesitant to buy in until we see how it works. We are in a 'show us' position," said Carl Seidel, associate director of technical affairs at Dupont Merck in North Billerica, MA and a past president of the Council of Radionuclides and Radiopharmaceuticals (CORAR).

Seidel's reservations stem from knowing how the DOE operates. "I don't know if the DOE will fully allow the Idaho facility to be run as it should be run—as a private company that can turn a profit

by operating at a lower cost," he pointed out. If the DOE tries to regulate the operation, the production costs could rise, causing a price increase for the isotopes. More importantly, the reliability of the shipments could be sacrificed. "A product with a short half-life must come on the day we ordered it for," said Seidel. "Previously, the DOE has been unreliable in producing what we needed when we needed it."

These concerns may be unwarranted if MAC Isotopes produces its products on time and at a competitive price. The company, however, must contend with certain DOE provisions built into the contract. One such provision requires that MAC Isotopes hire labor represented by the Oil, Coal and Atomic Workers Union and to pay them union rates and benefits. "It would be cheaper for us to do as much of the work in-house as we can, so this adds to our overhead costs," said Laflin. "But we understand the need to keep jobs and maintain a community out here."

Will Nuclear Medicine Benefit?

The DOE's privatization efforts hold a mixed bag for nuclear medicine. The field could gain if prices for isotopes fall; radiopharmaceutical prices would decline as well, which means procedures could be less costly to perform. Nuclear medicine research grants, however, could disappear as a result of privatization. "The question is whether any company will be willing to put money into research isotopes that may not have any market value," said Richard Reba, MD, a professor of radiology and chief of the nuclear medicine section at the University of Chicago. "It remains to be seen whether nuclear medicine can benefit from privatization."

Reba fears that an isotope production company may not be willing to produce, say, copper isotopes for cancer therapy research or enriched iron for neonatal research if there is a greater demand to produce profitable isotopes. Furthermore, what little profit the DOE did make from its isotopes had gone back to the DOE partially to fund grants for research. If private corporations reap the profits, these funds may no longer be available for grants.

In addressing these concerns, Laflin said his company will "probably be more responsive to research needs" than the DOE. Unlike the government whose support of research programs relies on Congressional funding, corporations can invest in research and development. "We will continue to produce those research isotopes that have been requested at Idaho in the past," said Laflin. "We will be in a position to support a given research program if a need is identified by the government." Although his promises may be sincere, only time will tell if they can be kept.

—Deborah Kotz

"We will be in a position to support a given research program if a need is identified by the government.

—Steve Laflin, the general manager of MAC Isotopes.

Should the DOE Market Molybdenum-99?

With its recent push to privatize, it seems strange that the Department of Energy (DOE) would be expanding its role in isotope production. However, that is exactly what the department decided to do on September 11 when it announced its final decision to go ahead with plans to produce ^{99}Mo. The DOE has begun converting the Annular Core Research Reactor and existing Hot-Cell Facility at Sandia National Laboratories in Albuquerque, NM. The decision was made after an environmental impact statement issued in the summer, found the project to be feasible. Energy Secretary Hazel R. O'Leary hailed this a "swords to plowshares" effort since the Sandia facility had previously been used for defense purposes.

"Within the next year, we will be providing 10% of the U.S. supply," said Owen W. Lowe, associate director for Isotope Production and Distribution in the DOE. Eventually, the facilities could provide 100% of the U.S. supply. "It is our intention to use the facilities as a backup," Lowe said. "In order to do this, we need some continuous process of manufacturing the isotope and putting it into the market."

Lowe admitted that "in a small way" the DOE would be competing with Nordion International, the Canadian company that currently supplies 80% of the U.S. supply of ^{99}Mo. Nordion is in the process of building two new reactors (one as a supplier and one as a backup) to replace its aging NRU reactor. The reactors, however, will not be complete until the year 2000. The DOE feels there is a need to have a reliable back-up supplier at least until then, according to Lowe.

Radiopharmaceutical manufacturers approached the DOE to become a back-up supplier of ^{99}Mo five years ago—before Nordion's plans to build the two Maple reactors. Although industry leaders have outwardly supported the DOE's plans and lobbied Congress for funding, they have been frustrated by years of delays. At this stage of the game, they are skeptical that the DOE will become a reliable supplier of ^{99}Mo.

"We don't know how reliable the shipments will be and what the pricing will be," said Carl Seidel, associate director of technical affairs at Dupont Merck in North Billerica, MA and a past president of the Council of Radionuclides and Radiopharmaceuticals. Seidel said none of the three major radiopharmaceutical suppliers in the U.S. have given the DOE firm commitments to buy ^{99}Mo from Sandia. "I think the DOE has an extremely big hurdle to overcome before they get any sales," he said.