

REPORT HINTS AT RESTRUCTURING OF DOE ISOTOPE PROGRAM

The revamped program is likely to stop making unprofitable isotopes unless separate research funding is appropriated for continued production.

With the U.S. isotope program on the verge of financial collapse, the Department of Energy is considering handing over control of production and enrichment facilities to a non-government corporation, judging from the recommendations of a confidential government study obtained by *Newsline* and interviews with DOE officials. If the recommendations are carried out, the revamped program would produce only those isotopes with potential to generate a net profit. For unprofitable isotopes with limited research applications, scientists and other users would have to seek separate research funding to support production.

Since 1990, the DOE's Isotope Production and Distribution Program has operated as a self-sustaining business under a plan worked out between Congress and the Bush Administration that gave the program a one-time appropriation of \$16 million. As a business the program has been a failure, running up a negative cash flow of \$8 million in two years. Even with an \$8.5 million line of credit from the U.S. Treasury and an additional appropriation of \$3 million requested in fiscal 1994, as organized now, the program is unlikely to ever produce a single curie of molybdenum-99, the product on which the DOE has gambled millions of dollars.

Conflicting Mandates

The program's troubles can be blamed partly on the conflicting mandates of federal legislation. The Atomic Energy Act of 1954 fosters research support while the 1990 legislation demands

profit-seeking. Or, as the confidential management study prepared at DOE's request by the consulting firm Arthur Andersen & Co. puts it: "The result of the conflicting mandates is a confused mission that hurts IPDP's business practices and impedes profitability."

Other crippling factors include massive and often unanticipated overhead burdens and cut-throat competition, mainly from Russia. (The DOE's share of the world market for stable isotopes plummeted from about 90% in 1990 to 50% after Russian suppliers entered the market).

The study, obtained through the Freedom of Information Act, contains a laundry list of recommendations intended to improve the program's dismal business performance ("improve delivery reliability", "reduce and stabilize overhead costs", etc.) and concludes that absent sweeping organization change, prospects for profit in the DOE environment appear "uncertain, at best."

Ultimately, the study advises the government to "carefully evaluate" alternatives to DOE operation of isotope production, such as leasing reactor and enrichment facilities to private companies. The warning was made with special emphasis in a separate section devoted to the molybdenum-99 initiative. Estimates of annual worldwide sales of Mo-99 exceed \$30 million, which is more than ten times the market for any other medical isotope. Tapping into the molybdenum market is perhaps the only way the DOE program could support itself. If unsuccessful, however, the molybdenum project "threatens

IPDP's very existence," in the words of the confidential study, which goes on to imply that the likelihood of failure is high. "The skills required to successfully produce and market Mo-99 reliably and profitably are less prevalent in government organizations than in private enterprises," the study comments euphemistically, before urging the DOE to "carefully consider" offers from the private sector to lease the Omega West Reactor at Los Alamos National Lab. Since the study was written, the option of leasing the reactor may have been lost with the discovery of a leaking coolant line that may cost the department millions to repair (see *Newsline*, April 1993, p. 20N).

The DOE now faces two basic paths: either revert to an internal program partially supported by taxpayers and partially supported by income from isotope sales, or join with some external entity in a government/industry joint venture along the lines of Atomic Energy of Canada, Ltd. and Nordion International.

The second path appeals most to Donald E. Erb, director of Isotope Production and Distribution. He envisions a not-for-profit entity, an "Isotopes U.S.A." with a board of directors representing the Secretary of Energy and leaders from industry, academic researchers, and professional societies, that would decide which limited-market isotopes are important enough to produce for research. At least one privately owned company has come forward with a proposal to operate the program as a not-for-profit organization. Mr. Erb says
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the study "goes right to the point of the matter—can you do the kind of things I'm trying to do from the bowels of government? I think the answer is no."

In stark contrast, radiopharmaceutical investigator Robert W. Atcher, PhD, of the University of Chicago, says his "worst nightmare" is the prospect of a private company running isotope production. Privatization like Canada is an inappropriate model, he says, "because

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the Canadians were making money before they went private." Dr. Atcher predicts that an industry/government joint venture would increase production costs. "A better solution would be to put all of isotope production within the Office of Energy Research and have no fantasies at all about this being a money making proposition."

Regardless of which route the Energy Department chooses to follow, the Arthur Andersen study recommends several obvious ways for isotope production to become more efficient. Overhead costs could be reduced substantially if the isotope program weren't forced to pay facilities costs that would be incurred regardless of isotope production activities. Were it not for such costs, the study estimates that the isotope program could have shown a \$1 million excess rather than an \$8 million deficit.

The study recommended closing unprofitable facilities and consolidating production at fewer sites, dropping out of markets where the government is no longer competitive, centralizing the management of marketing efforts rather than leaving much of it to each laboratory, improving delivery reliability,

appointing product managers and holding them responsible for product profitability.

Supporting Research Isotopes

Beyond these basic business tips, the study concurs with what many scientific investigators have been saying for the past two years: The DOE must define the difference between commercial and research isotopes, and then decide which research isotopes are important enough to produce using money from tax payers.

Given the existing self-supporting structure of the isotope program, Arthur Andersen states firmly that the DOE should simply stop making unprofitable isotopes, unless separate research funding has been appropriated for continued production. This straightforward statement for separate funding for research isotopes is

applauded by nuclear medicine investigators and other scientists who use radioisotopes in their work. "This at least forces Congress to face the issue of support for research isotopes," says the incoming president of the Society of Nuclear Medicine, Richard Reba, MD of the University of Chicago.

"They're telling the DOE to address the same problem we've seen for years, the need for separate funding for research isotopes," says Michael J. Welch, MD of Washington University's Mallinckrodt Institute of Radiology. "Indirectly, that's what the Society has been recommending by trying to get the DOE to fund the National Biomedical Tracer Facility separately."

Other researchers, such as Wynn Volkert, PhD, of the University of Missouri, express concern about the mechanism for deciding which isotopes will be produced. Dr. Volkert says, "If the DOE had a budget to support, say, the NBTF, and an oversight committee could decide what were the best isotopes to produce for research, I think that would be fine."

J. Rojas-Burke

LAMPF

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moment we're projecting January 1996."

While nuclear medicine investigators and clinicians lament the early demise of LAMPF operations, they are not surprised. And even investigators dependent on accelerator-produced radioisotopes for their research are lukewarm about efforts to keep LAMPF open. Many are pushing instead for the establishment of a National Biomedical Tracer Facility that would house a powerful accelerator dedicated to production of radioisotopes and related research and teaching.

"LAMPF hasn't been worth too much in the last couple of years," says Gerald L. Denardo, MD, of the University of California at Davis, who is developing cancer therapies using copper-67 labeled antibodies.

Cancer Treatment Stalled

Even prior to the announcement of LAMPF closing, supply of radioisotopes "has been chaotic at best," says Dr. Denardo. "We've had a very uncertain supply of radionuclides that are vital for clinical research as well as care of patients." Dr. Denardo and collaborator (and spouse) Sally J. Denardo, MD, have struggled through preliminary trials of copper-67 labeled antibodies to treat people afflicted with lymph node cancers.

Despite knowing for many years that ⁶⁷Cu is one of the best radionuclides for cancer therapy, researchers have been hamstrung by limited availability. "Supply problems have really slowed its development greatly," Dr. Gerald Denardo says. So extremely promising work with ⁶⁷Cu remains largely unexplored. The Denardos have managed to treat three patients who were dying from leukemia or lymphatic disease despite conventional treatment. Of the two who responded to radioimmunotherapy, one patient remained completely free of disease after more than three years.

Dr. DeNardo says that with LAMPF