

fallacy," in his paper, "How Dangerous Is Low Level Radiation?" (presented at the Royal Society of Canada Symposium on Risk Management, Ottawa, Ontario, October 18-19, 1993).

Researchers and policy makers, both in and out of the EPA, are obviously far from consensus on a matter that could cost up to \$10 billion per year (in some estimates) to theoretically save about 100 lives—if there is any risk at all. Curiously, after doing his mathematical model on radon

ingestion, Dr. Crawford-Brown has proceeded to study issues in the philosophy of science, on such questions as what level of evidence we have when we make decisions about theory and policy, why do we begin to debate certain topics, etc. If his line of inquiry is any example, a regulation calling for a radon MCL of 300 pCi/liter in drinking water may lead to widespread meditation on the relation of science and policy.

Lantz Miller

NBTF HOPEFULS SCRAMBLE FOR DOE GRANT

A national year-round isotope supply moves closer.

THE DOE'S OCTOBER 14, 1993 announcement inviting grant applications for project definition studies for a National Biomedical Tracer Facility (NBTF) was a step toward materializing what the nuclear medicine community has advocated for years. DOE anticipates that it will award \$300,000 to up to five applications for NBTF project definition studies. The announcement was also the starting bell for a competition among groups that have expressed interest in hosting such a prestigious and potentially profitable facility. But some critics say the DOE's plan to make biomedical isotope provision a commercially viable private enterprise is not the most cost-effective way to provide those isotopes.

The call for applications, appearing in the *Federal Register*, Vol. 58, No. 197 (Thursday, October 14, 1993, pp. 53197-53198), stated a four-pronged goal for the project definition study: to define the NBTF's design, cost estimate, and construction schedule; to address the facility's radioactive waste management; to develop a business plan for its commercial operation—including reimbursement to the federal government for construction; and to determine whether an NBTF would satisfy demands for radioisotopes—and whether it could be completely operated by a private enterprise. Though the request for proposal (RFP) states that the NBTF may be either a new facility or modification of an existing one, the emphasis on private enterprise leaves the RFP unclear as to whether it allows applications from

federal labs which may already have some of the necessary infrastructure.

"We are very interested in an NBTF being sited at Los Alamos or institutions we're associated with," said Eugene Peterson, PhD, director of isotope production at the Los Alamos National Laboratory in New Mexico. But he pointed out that, through indications in the wording that favor the private sector, the RFP seems to make it difficult for national labs to apply. "If you don't take advantage of what is available at national institutes, it will be difficult to do this [project] within costs that could be allocated," he said, citing the complexities of operating an accelerator facility, the mire of regulations, and waste handling and disposal. "It seems to me that taking advantage of institutions that have the infrastructure would be only to the cost advantage," he said. "Still, we'll look into how we can participate within the requirements outlined in the RFP."

Other groups, though not national labs, are already setting up joint ventures between government (usually state or local) and the private sector. The University of North Texas (UNT, Denton, TX) is collaborating with a for-profit company, North Texas Research and Development Corp. (NTRD, Denton, TX) on a facility that this partnership will outline in a grant application. Raleigh Schaffer, PhD, associate vice president for research and dean, UNT Graduate School, explained that NTRD will raise money for work on radionuclide production, and UNT, using government funds, will handle research and education. This set-up takes advantage of the expertise of both sectors involved. Dr. Schaffer felt that certain other advantages to the plan would add to its suitability for the NBTF: the north Texas location's centrality to the rest of the country and proximity to an international airport; a 25-year history of accelerator tech-

nology on campus (which hosts an annual conference on accelerators in industry); and UNT's educational programs like health physics and biochemistry.

Lon Morgan, NTRD president, said that to make the project economically viable and satisfy market demands, his team planned on the 100meV, 1 mAmp proton machine (the standard for this project) making four radionuclides per run (dividing the 1 mAmp into 100-200 uAmp per target). Thus, one run may produce ^{67}Ga , ^{201}Th , ^{111}In , and ^{99}Mo . He described the tricky economics of the situation: "To provide for the staff and operations will take about \$10 million per year, so we must at least sell that much per year." The total annual national market for radionuclides is about \$80 million, he said, and "this facility will supply about 10% of that," or about \$8-10 million. Thus, the profit margins are narrow. The approximately 100 μAmp access will be used for research radionuclides— ^{41}Ca , ^{67}Co , etc.

Biomedical Research Foundation of Northwest Louisiana (BRF, Shreveport, LA) seeks perhaps a more unusual collaboration. BRF would serve as an umbrella organization, allowing other groups to contribute funds. "This situation requires a new strategy," said Tom Tierney, BNF executive director, with government, industrial, and academic components involved. "We feel we have a strong track record in blending these resources into partnership. We raise money from our community, so we're developing a *nouveau* way of funding." Louisiana has a particular interest in the NBTF project because of an outlay it made for PET at BNF—for a 160,000 ft² research facility with 56 labs. Tierney said that BNF is also considering a joint venture with public and private community hospitals which share its PET facility, so that BNF would act as a broker for a "rare" resource (radionuclides).

But Suresh Srivastava, PhD, senior scientist at Brookhaven National Laboratory Medical Department and president of SNM's Radiopharmaceutical Council, has an entirely different outlook. He stated, "The national laboratories cannot apply. The language of the RFP cites certain things that make a national laboratory not an appropriate institution to respond." Brookhaven has not investigated joint ventures and similar options as other institutions have, "because of what the RFP has specified. In the meantime, we'll just keep a low profile and wait and see what the outcome of the applications is."

Dr. Srivastava described another possible outcome. "Since isotope production is one of the [NBTF's] main functions, and since it can be done privately, then the government should ask the

private sector first and then decide which one can do this with its infrastructure," he said. "You cannot do this [the NBTF] from scratch. But I assume the DOE will look at all the applications and present them to the IOM (the Institute of Medicine) panel, which will advise the DOE in the decision process. Then I think they will come back to the national laboratories because no one else can handle it." The Brookhaven Linac Isotope Production Facility recently was appropriated \$6 million for FY1994 (see *Newsline*, June 1993) so it could begin an upgrade for producing certain isotopes year round instead of a few months of the year, and some IOM members are investigating Brookhaven for the possibility of an upgrade to an NBTF, as a report due July 1994 will evaluate. Dr. Srivastava said that such further upgrade, which U.S. Representative Mike Synar (D-OK) is also investigating, had its pluses and minuses, the main problem being the machine's age.

Dr. Srivastava described the idea of a full recovery of cost of a facility as "a fantasy. Many of these isotopes are like orphan drugs, very specialized." Another problem with completely privatized, commercial isotope production, he pointed out, was that of Russian economic competition. "They will undercut us [to the point where] we can't compete; it would be silly to try," he said. The continually plummeting ruble will give the Russians an ongoing advantage in this respect. For example, a Russian group recently offered ^{68}Ge to DuPont, which asked Brookhaven to match the price. "Of course, we couldn't," he said.

But doubts about the DOE's approach to the problem does not hinder other prospective applicants. Paul Ziemer, PhD, head of the School of Health Sciences at Purdue University (Lafayette, IN), expressed dismay over "some of the issues" in the RFP, although his group is investigating several avenues for its DOE grant application. He decried "the way the DOE has framed the business plan for this"—specifically, the requirement for including on the application the prospective NBTF's plan for reimbursement to the government for the cost of developing the program. "As this particular project was defined by the nuclear medicine community, the facility would not compete with the private sector for common isotopes," Dr. Ziemer said. "It was seen more as a specialized provider, and for research and education, not as a profit-making [enterprise]."

Nonetheless, his institution plans to team up private groups for the NBTF's production processes with some groups on campus for supplying research and education. Purdue has the advantage of having its own airport within a mile

"The language of the RFP cites certain things that make a national laboratory not an appropriate institution to respond," said Dr. Srivastava.

of campus and programs in radiation safety, radiopharmacy, radiochemistry, health physics, nuclear engineering, and nuclear physics, all of which are working in concert on the project. Purdue has organized an executive committee of deans and vice presidents to provide oversight and policy for the NBTF application process. An Indiana state agency is also involved, analyzing the prospective facility's economic impact on the area. In an ironic twist to the DOE's idea of avoiding federal dependence for the NBTF, Dr. Zeimer said, "Wherever this facility goes, there will have to be state support."

But Donald Erb, director of DOE's Isotope Production and Distribution program, remains confident that the direction the DOE has taken for the NBTF is the best. "We're trying to break new ground and see what new arrangements are possible in cost-sharing," he said. "Knowing the way

the bureaucracy works, and that there's a commercial accelerator capacity in this country, this is the way to answer the needs of radiopharmacy professionals: to form a partnership to move this forward, using industry plus government." Dismissing those critics who say "we should just give away appropriations," Mr. Erb asserts that the DOE approach DOE to siting and other aspects of NBTF development will lend a healthy element to the process. In a January 11, 1993 letter (*see Newsline*, April 1993, p. 18N), SNM and ACNP advised William Happer, PhD, director of the Office of Energy Research, that to one of the healthiest elements DOE can offer in the process is the use of peer review every step. Mr. Erb stated that the decision of who will grant the funds will probably be made by the director of energy research.

Lantz Miller

HIGHLIGHTS OF FIFTH ANNUAL INTERNATIONAL PET CONFERENCE

Cost-effectiveness and competitiveness are the key words on applications in neurology, cardiology, and oncology

THE INSTITUTE OF CLINICAL PET sponsored the Fifth International PET Conference in Tysons Corner, Virginia, October 28-31, 1993. The conference had as one theme the practicality of PET, but with health care reform in the air, this took on the aspect of PET's competitiveness in the medical marketplace. In sessions on neurology, oncology, and cardiology, lecturers returned to PET's position among other diagnostic tools, among therapies, and in relation to surgery, to show PET can cut costs by avoiding expensive medical procedures.

PET's Cost-Effectiveness

In fact, the first day's entire second session was devoted to "Cost-Effectiveness of PET." Elizabeth F. Brown, MD, medical director at Aetna Health Plans (Chicago, IL), addressing the problem of managed competition in the future health

care system, discussed the use of technology assessment (TA)—an analysis of a technology's safety and effectiveness. Aetna uses TA on medical technologies in determining coverage for PET scans. "We need a process to apply legally to all things from PET scans to quackeries," she said. "We need evidence that a diagnostic technology will change a patient's management." The evidence must appear in a peer-reviewed journal, she said, though this kind of information is limited in the literature (often a study is written by someone whose career is interested in promoting PET, she added). "We'd like more information from specialty societies."

On the issue of cost-effectiveness, Dr. Brown said that her company does not use it now in reimbursement decisions because nothing in the literature allows them to do this; Aetna must rely on what is in the literature, which has few studies focusing on cost-effectiveness as the gist of the study; and something is cost-effective only if it used in a cost-effective way—which is difficult for an insurance company to assess. Thus she called for the development of practice guidelines which cross the various sub-specialties. "PET scanning and diagnostic imaging are high profile," she said. "In the future, they will be under the 'microscope' in cost-cutting discussions."

Myrwood C. Besozzi, MD, director of Nuclear