

UNCERTAINTIES FACE MEDICAL ACCELERATOR PROPOSAL

Nuclear medicine researchers say the need is as urgent as ever, but developments could slacken support for the National Biomedical Tracer Facility.

“The NBTF is becoming a really hard sell.”

DOES THE UNITED STATES STILL need a National Biomedical Tracer Facility? Expert panels convened by the federal government since 1988 have repeatedly concurred that the U.S. Energy Department should give top priority to building a particle accelerator dedicated to the production of radioisotopes used in medicine and research.

But lately, a more pertinent question seems to be, Can the country get along without an NBTF? And nuclear medicine researchers are becoming increasingly concerned that the federal government soon may decide that the answer to that question will be yes.

The Society of Nuclear Medicine and the American College of Nuclear Medicine first proposed the establishment of a National Biomedical Tracer Facility in 1991 as a means to solve the chronic radioisotope supply problems that have long hampered biomedical researchers.

At that time, it looked as though North America was on the brink of prolonged shortages of accelerator-produced isotopes. Many radioisotopes with promising medical applications, especially as agents for cancer therapy, are still produced in limited quantities at facilities run by the Energy Department primarily for physics research.

These isotope programs, the Los Alamos Meson Physics Facility (LAMPF) and the Brookhaven Linac Isotope Production Facility (BLIP), operate intermittently and are never operated all year round. The resulting disruptions in production have made it nearly impossible for clinical trials of new therapies to go forward without interruptions.

Worse still, one facility or the other, or both, have been threatened with closure due to lack of funding and changing priorities at the Energy Department. To some extent, these problems persist.

New Wrinkles

Yet over the past several months several developments have emerged that experts believe will make it more difficult to convince the federal government of the importance of funding the NBTF.

First, LAMPF has survived the budget ax and now has a new mission that could keep it in business for years: defense production. The Energy Department had set aside money to dismantle the venerable accelerator last year, but now the machine will be used by defense scientists to test the feasibility of producing tritium, an isotope with a 13-year half life, used in nuclear bombs. At the same time, production of isotopes for biomedical use will continue.

Second, the BLIP at Brookhaven National Laboratory is well on its way to upgraded production capacity thanks to \$5.8 million from the Energy Department's Office of Energy Research. Despite across-the-board budget cuts ordered by Energy Secretary Hazel O'Leary, the accelerator and laboratory improvements at Brookhaven are still due for completion by August 1996.

The project calls for replacing accelerator parts and beefing up the cooling system so the machine can run more reliably at higher energies for longer periods of time, said BLIP Director Leonard F. Mausner, PhD.

Depending on operating funds, the new, improved BLIP will be able to run continuously 46 weeks per year versus the current 18 to 20 weeks, Mausner said. And with a higher intensity accelerator beam, production capacity will be greater and higher specific activity isotopes will be possible.

But the development that has nuclear medicine researchers talking the most is taking place in Texas. A nonprofit corporation affiliated with the University of North Texas has gained assurances of funding from the Energy Department to launch an accelerator production facility at the now defunct Super Conducting Super Collider. (See *Newsline*, October 1994, p. 19N.)

The North Texas Research and Development Corporation at press time in early November was still awaiting final approval of a settlement agreement between the Energy Department and state officials in Texas, which threatened to sue to recover state investments in the SSC. But North Texas officials are confident of gaining \$65 million from the Energy Department to convert an

existing accelerator at the remote Waxahachie site into a cancer treatment and isotope production center.

"I would think it's going to happen," said Rolie Schafer, associate vice-president for research and dean of the School of Graduate Studies at the University of North Texas, Denton.

Murky Future

What does it all mean? The production capacity for radioisotopes is headed sharply up. Consequently, "The NBTF becomes a real hard sell," as Brookhaven's Dr. Mausner put it. "Everything is very muddled because of this SSC project."

"A lot of us are worried how this SSC proposal will affect the NBTF," said the chairman of the Society's committee on isotope supply, Wynn A. Volkert, PhD, a research scientist and professor at the University of Missouri in Columbia. He said advocates of the NBTF have two concerns: The creation of a new accelerator in addition to the survival of the older ones could lead congressional officials to conclude that isotope supply problems are no longer what they used to be. And if the Energy Department commits millions to the Texas group, less money would be available for other projects.

North Texas officials insist that the SSC project shouldn't undermine the NBTF because it would not produce many of the rare isotopes used now only by biomedical investigators. Nor would the facility support research projects and graduate training programs.

"It's a pretty bare bones production facility," said Schafer. "I hope it doesn't undermine the NBTF." Schafer said that his university is among

the five competitors seeking to build the NBTF. The North Texas proposal calls for establishing a center in Denton near the university and entirely separate from the SSC site.

Influential Study

One thing is certain: The fate of the NBTF proposal now rests largely with a group of experts representing all of the fields that use separated isotopes. A congressional oversight committee explicitly asked the National Academy of Sciences' Institute of Medicine to make a recommendation about whether the government should build an NBTF. After many delays, the IOM has tentatively scheduled to release their final report on December 13 in Washington, DC.

Nuclear medicine researchers are anxiously awaiting to see if the panel judges in favor of proceeding with the NBTF. "If the Institute of Medicine says there is no need, it would be a major setback in convincing legislators that they should fund the NBTF," said David Nichols, a government relations spokesman for the Society and College.

Meanwhile, said Dr. Volkert, "We still have the same isotope supply difficulties—There is no facility that operates year round at this point."

The Department of Energy has awarded \$2 million in grants to five institutions to develop preliminary proposals for the NBTF. In addition to North Texas, the institutions are the University of Alabama, the University of California at Davis, the University of Southern California, and Purdue University. The Energy Department next year is supposed to pick one or more sites and provide them further funding to design competing proposals for a final facility.

J. Rojas-Burke

SNM AND ACNP URGE NRC TO STOP REGULATING NUCLEAR MEDICINE

LEAVING NO DOUBT ABOUT WHERE they stand, members representing the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) presented a united front, testifying before the National Academy of Sciences' Institute of Medicine that the U.S. Nuclear Regulatory Commission (NRC) should stop regulating the medical use of radioactive materials.

"The NRC's Medical Use Program is a dys-

functional anachronism that should have ended at least two decades ago.... NRC no longer runs a safety program; it runs a 'protection racket.' Its user fees are more like extortion than valid reimbursement for services rendered," testified Carol S. Marcus, PhD, MD, representing the ACNP.

James J. Conway, MD, president of the SNM, expressed serious concern about "the overextension of statutory authority by the NRC," the agency's "intrusion into the practice of medicine,"