The Department of Energy's Role in Isotope Availability for Nuclear Medicine Research

Until recently, the major successes in the medical use of radioisotopes have been in diagnostic applications. However, breakthroughs in molecular biology have led to increasing interest in the application of radioisotopes for the treatment of disease.

For example, the development of human monoclonal antibodies and a better understanding of how peptides interact with cells, and combining radioisotopes with these agents, is leading to potential new therapies for the treatment of cancer. In addition, radiopharmaceuticals are now used to ease bone pain resulting from metastases of cancer, and the temporary insertion of ^{192}Ir carriers into arteries after angioplasty is showing excellent results in the prevention of restenosis.

Many applications currently await development. These applications will require the production of new isotopes, improved production techniques to generate higher specific activities for isotopes currently in use and improved delivery systems. The Department of Energy (DOE) intends to play a leading role in meeting the future challenges of isotope availability.

Isotope Production and Distribution

The peacetime supply of isotopes began in 1946 when the first shipment of ^{14}C, made in the graphite reactor at Oak Ridge National Laboratory, Oak Ridge, TN, was provided to a hospital in St. Louis, MO. Within a year, Oak Ridge National Laboratory had produced and distributed 60 different isotopes, chiefly ^{131}I, ^{32}P and ^{14}C. These isotopes were used in the developing field of nuclear medicine and as tracers for academic, industrial and agricultural research. Since then, a substantial infrastructure has been built around the use of isotopes, and isotopes are currently a vital part of U.S. medical, research and industrial activities. The DOE's isotope production activities have also increased with the growth in demand. Today, the DOE produces and distributes over 200 different stable and radioactive isotopes from four of its national laboratories.

The DOE is also involved in developing new uses for isotopes. For instance, for many years the National Institutes of Health (NIH) and the DOE have shared responsibility for therapy research in nuclear medicine. The DOE provides the isotopes and sponsors research in chemistry and biology, including preclinical feasibility studies in humans, to develop radiopharmaceuticals. After radiopharmaceuticals have been initially developed by the DOE, NIH begins sponsoring research into their applications, including extensive human clinical trials, in preparation for Food and Drug Administration approval. Thus, the activities of the DOE and NIH complement each other.

A New Approach to Research Radioisotope Availability

Two organizations within the DOE support nuclear medicine research activities. The Office of Energy Research has sponsored activities such as the development of medical isotope technology, radiopharmaceuticals and instrumentation as well as animal testing and preclinical human feasibility studies. The Office of Nuclear Energy, Science and Technology has focused on maintaining the production facilities at national laboratories, improving current isotope production capabilities and developing production methods for new isotopes.

As a new initiative in fiscal year 1998, the DOE proposed that the Office of Nuclear Energy, Science and Technology sponsor an effort to make accelerator-produced isotopes available to researchers for 10 to 12 months in each of fiscal years 1998 and 1999 by coordinating production among the DOE's facilities at Brookhaven National Laboratory (Brookhaven, NY), Los Alamos National Laboratory (Los Alamos, NM) and the Tri-University Meson Facility in Canada. This effort recognizes the long-standing desire of the medical research community for a year-round supply of accelerator-produced radioisotopes at affordable prices. However, fiscal year 1998 funding will not be sufficient to meet this commitment, and year-round availability must wait until at least fiscal year 1999. Assuming this new approach to increasing availability of accelerator-produced radioisotopes is successful, the DOE anticipates expanding this effort to the research isotopes it produces by other means.

Prices of isotopes used in research and development usually are set at a level that provides a reasonable return to the U.S. government but does not discourage their use. When possible, the isotopes are sold on a full-cost-recovery basis. It is important that the DOE maximize revenue whenever possible; this makes the isotope production and distribution program less dependent on congressional funding—and the American taxpayer—for support of its activities.

We do, however, recognize that research funds are limited. To address the cost issue for the research isotopes generated under this new initiative, the DOE has committed to cooperate on selected research projects by making isotopes available at less than full cost. The DOE is developing criteria to guide selection of projects to support in this manner. The criteria will include consideration of the source of funding for research projects, funds available for isotope supplies and scientific merits of the research.

Evaluation of research projects will require an advisory process regarding the selection of projects to support. In general, the advisory process will include methods to formulate requests for proposals, peer review of proposals and project selection. Research project support could be in the form of direct grants to researchers within both the DOE's complex and the medical and university community or cooperative agreements with not-for-profit organizations.

Facilities

Isotopes in the U.S. are produced in accelerators, in reactors or by processing byproduct materials produced by the DOE's weapons program. Essentially, these methods are complementary rather than competetive. The DOE's national laboratories offer unique isotope production facilities, specifically the calutrons, accelerators and reactors.

The electromagnetic calutrons at Oak Ridge National Laboratory produce enriched stable isotopes. Many of these isotopes, such as ^{88}Sr, ^{201}Tl and ^{68}Zn, are required to produce other isotopes used to help diagnose cancer and heart disease and provide cancer therapy. Russia is the only other nation that has a similar large-scale electromagnetic separation facility.

Accelerator production of radioisotopes is accomplished by the DOE at two sites. The Los Alamos Neutron Science Center provides a proton beam or neutrons for radioisotope production at Los Alamos National Laboratory, and the Brookhaven Linear Isotope Producer provides similar capability at Brookhaven National Laboratory. The DOE intends to maintain these facilities for isotope production. Upgrades to the hot cell facilities for the Brookhaven Linear Isotope Producer have recently been completed, and a new radioisotope production facility at the Los Alamos Neutron Science Center is scheduled to be completed by 2000.

Two major DOE reactors, the High Flux Isotope Reactor at Oak Ridge National Laboratory and the Advanced Test Reactor at Idaho National Engineering Laboratory (Idaho Falls, ID), currently produce radioisotope products and services that cannot be produced elsewhere in the country. The DOE anticipates continuing to operate these reactors for the foreseeable future. By fiscal year 1999, a third reactor, the Annular Core Research Reactor at the Sandia National Laboratories in Albuquerque, NM, will have been modified to begin producing the short half-life radioisotope ^{99}Mo. This reactor will be dedicated to radioisotope production.

In addition, the DOE is reviewing other facilities that can produce radioisotopes as a secondary mission. For example, the DOE is currently evaluating methods for tritium production to support the U.S.'s weapons stockpile. Part of this evaluation includes review of the economic and technical feasibility of using the Fast Flux Test Facility in Richland, WA, or the proposed Accelerator Production of Tritium Facility to produce medical radioisotopes as a secondary mission to tritium production. With the appropriate infrastructure in place, it is believed that either of these facilities could produce a wide range of radioisotopes for medical research and therapeutic and diagnostic procedures.

Future Role

The use of radioisotopes for diagnostics, therapy and other medical research holds great promise. The basis of this promise is a reliable, steady supply of isotopes at reasonable prices. The DOE sees a great future for nuclear medicine and wants to work with the nuclear medicine community in a positive way to enable progress in all aspects of this vital discipline. The DOE will continue to operate its unique facilities to maintain an appropriate inventory of isotopes and will continue to support nuclear medicine research as a logical extension of the current scope of its activities.

However, how this role will be defined in the future depends a great deal on the ability of isotope customers and stakeholders—such as the nuclear medicine community—to educate the public, local elected officials and Congress on the benefits of nuclear medicine. The nuclear medicine community needs to unify itself behind a coherent program to expand its contribution to the health, well-being and quality of life of humankind. The DOE stands ready to work with the nuclear medicine community to ensure that the promise of nuclear medicine is fulfilled.

—Terry R. Lash
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Annual Meeting Preview

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representatives from over 100 major manufacturers and suppliers of nuclear medicine equipment, products and services. On the exhibit floor and during user meetings, these companies will display and demonstrate the latest advances in computers, imaging cameras, dose calibrators, radiation safety products, publications and radiopharmaceuticals.

Plenary Session and Other Activities

The Annual Meeting will open with the Plenary Session, at which the second annual Henry N. Wagner, Jr., Scientific Lecture will be given by Frans H.M. Corstens, MD, FRCP, University Hospital, Nijmegen, the Netherlands, who will discuss new clinical nuclear medicine procedures. SNM's de Hevesy Award will be presented to Nagara Tamaki, MD, and Heinrich R. Schelbert, MD, PhD. The Aebersold Award will be presented to Gerd Muehllehner, PhD, UGM Medical Systems, Philadelphia, PA. The ERF's prestigious Cassen Prize will be awarded to Henry N. Wagner, Jr., professor of medicine, radiology and environmental sciences, The Johns Hopkins Medical Institution, Baltimore, MD. Also, for the first time, a preview of the week's continuing education courses will be presented during the Plenary Session by SNM president H. William Strauss, MD.

A variety of social and recreational opportunities are available to attendees wanting a respite from the educational and scientific programs. In addition to the welcome reception and the SNM-TS party, attendees can explore Toronto's numerous restaurants, galleries and museums, theatrical offerings and other cultural opportunities.

As in past years, the Annual Meeting will conclude with Henry N. Wagner, Jr., MD's, 21st overview and highlights of the scientific research presentations.

—Eleanore Tapscott