National Radionuclide Production Enhancement (NRPE) Program: Meeting Our Nation's Need for Radionuclides

BACKGROUND

Nuclear Medicine is a well-established diagnostic and therapeutic discipline that uses small quantities of radionuclides (radiopharmaceuticals) to diagnose diseases and slightly greater quantities to treat diseases. The diagnostic procedures provide effective ways to gather functional and pathophysiologic, as well as anatomic information that would otherwise not be available by other imaging procedures, or that may require biopsy or exploratory surgery. In addition, nuclear medicine procedures can treat certain diseases and can also determine the effectiveness of therapeutic intervention. No other existing single modality can perform all these functions. Furthermore nuclear medicine imaging procedures often identify abnormalities very early in the progress of a disease – long before many medical problems are apparent with other diagnostic tests. An estimated 16 million nuclear medicine diagnostic and therapeutic procedures are performed each year in the United States and the number of procedures has continued to grow steadily.

In imaging, the radiopharmaceuticals are detected by special types of cameras (SPECT, PET, or gamma) that are coupled with computers to provide precise pictures of the internal parts of the body being imaged. In treatment, radiopharmaceuticals go directly to the organ being treated. The amount of radiation in a typical nuclear imaging procedure is comparable with that received during a diagnostic x-ray, and the amount of radioactivity received in a typical treatment procedure is kept within safe limits.

Today, nuclear medicine procedures are essential to the management of large numbers of patients in many medical specialties, from pediatrics to geriatrics and from oncology to cardiology, neurology and psychiatry. There are nearly 100 different nuclear medicine imaging procedures current in use. Common nuclear medicine applications include diagnosis and treatment of hyperthyroidism (Graves' Disease) and thyroid cancer, cardiac stress tests to quantify heart function, diagnose coronary heart disease and determine the effectiveness of coronary artery bypass surgery and angioplasty. Other uses include bone scans to determine if cancer has spread, lung scans to diagnose pulmonary embolism and the early diagnosis of Alzheimer's disease. New and innovative nuclear medicine treatments that identify and characterize molecular targets within the body are revolutionizing our understanding of pathophysiology, genesis and approach to a range of diseases and conditions, primarily cancer and cardiovascular diseases.

Because of these new and creative nuclear medicine procedures, the Nation needs a consistent, reliable supply of domestic radionuclides for medical applications and innovative research uses. Today, new radioisotopes for diagnostic and therapeutic uses are not being developed as the national radioisotope infrastructure is chronically under funded at the Department of Energy (DOE). New and innovative nuclear medicine treatments will require reliable supplies of domestic radionuclides. Radiolabeled chemicals for proposed new treatments are critically important to the drug development process. By constraining innovative biomedical and new drug development research that relies on using radiolabeled probes, the medical community will not benefit from valuable discoveries for the diagnosis and treatment of millions of Americans.

THE PROBLEM

It is because of these successful and useful clinical applications and much needed innovative research initiatives, that the demand for a variety of radionuclides is rising exponentially. However the majority of radionuclides used in daily applications today are imported on a daily basis and those required for innovative research are either available sporadically and only in limited quantities or not at all.

Today in our Nation there is only one research reactor, the University of Missouri Research Reactor) (MURR) that provides reactor-produced radionuclides for therapeutic applications. However it has a low power (10MW) that enables it to produce only relatively small quantities of radionuclides at a low specific activity (a few radioactive atoms and a much greater number of non-radioactive atoms) that limit their use.

In addition, the U.S. has no functional accelerator that can provide cyclotron-produced radionuclides needed for specific diagnostic and therapeutic applications or creative research initiatives. Commercial or university based small and large accelerators exist but they produce only limited quantities of a small number of radionuclides, primarily for routine, approved uses.

The demand for radionuclides is rising rapidly due to the blossoming therapeutic and diagnostic applications of nuclear medicine. The future of life-saving therapies and cutting edge research in nuclear medicine and molecular imaging depends on a reliable and reasonably priced supply of radionuclides. The challenge for our Nation is to secure a reliable and enhanced domestic radionuclide supply for the growing medical need of our patients and for research

There have been a dozen committees, task forces, and IOM (Institute of Medicine) reports during the past 20 years that have examined the issue of reliable radionuclide availability for biomedical research and commercial use. With some minor differences of opinion about specific radionuclides or the rate of growth of medical radionuclide usage, these reports are generally in agreement and all identify the same trends, which are:

- Predict increased growth in radionuclide use
- Expect shortages of some major radionuclides
- Lack of a reliable supply of research radionuclides produced at a reasonable cost
- Inability of DOE to produce radionuclides at a regular rate and at a reasonable cost
- An over-dependence on non-U.S. radionuclide sources

THE ANS BELIEVES - - THE SOLUTION

In order to seek a solution to this bleak situation, a task force consisting of physicians, basic scientists and industrialists hailing from different professional organizations was formed. Their report includes the following recommendations:

- A national program should be established to meet the national need for radionuclides. This program should develop the capability to produce large quantities of radionuclides to maintain existing technologies and to stimulate future growth in the biomedical sciences. The overall production capacity must be sufficient to insure a diverse supply of radionuclides for medical use in quantities required to support research and clinical activities. Radionuclides for clinical and research applications should be supplied reliably and with diversity in adequate quantity and quality;

- Collaborate with medical, and industrial users to assess radionuclide needs and transfer technologies to accelerate applications;

- Facilitate the transfer of commercially viable radionuclides programs to the private sector;

- Invest in research and development to improve radionuclide production, processing, and utilization;

- Monitor continuously the radionuclide needs of researchers and clinicians; and

- Establish an education program to ensure that the next generation of nuclear and radiochemists are trained and available to support the Nation's needs. (NOTE: No funds are requested for this goal but the NRPE will provide the infrastructure, personnel and environment, to support an education program.)

The American Nuclear Society (ANS) endorses these recommendations.