American Nuclear Society Issue Paper on Isotope Production and Research

Summary

Radioactive and stable isotopes play a critical role in U.S. national defense, health care, industry, and research. The American Nuclear Society believes the U.S. Government should take urgent steps to shore up the isotope production infrastructure.

Why are Isotopes Important?

Isotopes, including both radioactive and stable isotopes, make important contributions to research, medicine, and industry in the United States and throughout the world. For nearly fifty years, the Department of Energy (DOE) has actively promoted the use of isotopes by funding production of isotopes at a number of national laboratories, nuclear medicine research, and research into applications and production of isotopes. The radiopharmaceutical and radiopharmacy industries have their origin in these DOE-funded programs. Currently, more than 10 million nuclear medicine procedures are performed each year in the United States, and it is estimated that one in every three hospitalized patients has a nuclear medicine procedure performed in the management of his or her illness.

A technician prepares a young girl for Positron Emission Tomography scanning, a

The fact that the uses of radioactive materials are ubiquitous in our society, giving rise to enormous economic and health benefits, is generally unappreciated by most Americans. Overall, the biomedical community uses more than 200 radioactive and stable isotopes for research, drug development, and diagnosis and treatment of human diseases. All of this is enabled by an abundant supply of isotopes that can meet the changing needs of a vigorous and growing research community. The medical and health uses improve the quality of life and save lives by early diagnosis and treatment of disease. In fact, 80–90% of all drugs that receive Food and Drug Administration (FDA) approval go through a research and development process that uses radioisotopes. At the same time, the costs of medical care are significantly reduced by the use of radioactive materials. The industrial uses improve public safety and increase the quality while reducing the cost of everyday products. If the widespread uses of radioactive materials are not maintained through research, it will not be possible for this country to sustain, much less expand, our high standard of living and advanced industrial economy.

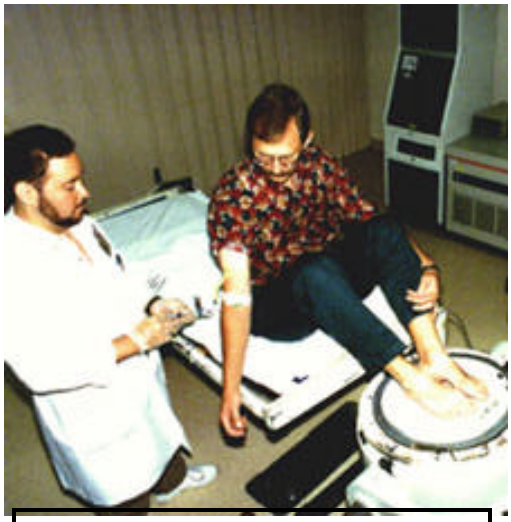
Many, including David Baltimore, Nobel Prize winner in physiology and medicine and president of Caltech, have pointed out that within the next 50 years a revolution in biotechnology could bring breathtaking advances in health, longevity, food supplies, and even energy supplies. Such developments will depend on robust federal support and an assured supply of radioisotopes from the DOE.

Current producers of radioisotopes in the United States and world today include governments that operate reactors and accelerators at national laboratories or institutes, and commercial companies that own and operate

accelerators. Very importantly, there are many partnership arrangements where companies lease irradiation space in government reactors or operate processing facilities in coordination with the government. In fact, the commercialization projects that the DOE has recently conducted successfully are all aimed appropriately at building partnerships, not at selling off or shutting down their unique production facilities.

What Should the U.S. Do to Support Isotope Production and Research?

Recent levels of federal appropriations have **not** permitted the DOE's isotope supply to keep pace adequately with the changing needs of the research community. The shortfall of radionuclides significantly inhibits progress in evaluating a host of promising diagnostic and therapeutic drugs in patients with debilitating and fatal diseases, examining fundamental basic science questions, studying human behavior and normal growth and development, and exploring the aging process and the products of transgene expression.



A patient receives a radioactive isotope injection to help determine the cause of his

A factor that compounds the problem of limited funding for radioisotope supplies is parasitic production. At all DOE production sites the radioisotope production mission must share the reactor or accelerator with other diverse programs for nuclear science, energy, or defense. The other sponsors are much larger than the isotope production and exercise considerable influence on the facility schedules and priorities. This "parasitic production" often yields a lack of priority for radioisotopes, especially for the smallest customers. The only complete solution to the problems of parasitic production is to take steps to provide dedicated, yet modest, facilities for radioisotope production in the future.

Federal isotope supplies are not focused on research needs. DOE sales of radioisotopes during recent years have been predominately to commercial suppliers. By dollar volume, over 95% of the sales were bulk isotopes for medicine (notably strontium-82, germanium-68, and others) and industry (notably iridium-192, californium-252, and others). Less than 5% were for research sales, though the number of shipments of specialty isotopes greatly outweighs the number of bulk radioisotope shipments, and the kinds of radioisotopes supplied to researchers are much more diverse. Of course, the commercial suppliers purchase radioisotopes from the DOE at full cost recovery, and the sales have a beneficial effect on allowing the system to offset its costs of maintenance. However, without increased federal support for research radioisotope production, this balance will be impossible to shift toward future research needs.

Federal appropriations for the DOE's Isotope Program have averaged only about about $20 million per year, which is divided among five DOE sites. At this level of support, the sites not only have difficulty supplying radioisotopes to researchers, but are also unable to maintain their infrastructure. **This situation needs to be corrected, with significantly greater funding for radioisotope production—$40 million per year—as well as the creation of a new initiative for dedicated, yet affordable, reactor and accelerator facilities. A recent study of radioisotope production and research needs identified the strong need for a dedicated 70 MeV accelerator and a dedicated high-flux, yet low-power reactor. The new Administration should call for the detailed evaluation and funding of these new, critically-needed facilities. The new Administration should also consider the potential use of the Fast Flux Test Facility, and existing reactor in Washington state, as a means to assure future U.S. access to needed isotopes.**