

Institute of Medicine Study Supports State Regulation of Medical Isotopes over NRC

For four decades, the Nuclear Regulatory Commission (NRC) has regulated commercial nuclear plants as well as the use of reactor-produced radioisotopes in medicine and biomedical research. For years, the Society of Nuclear Medicine (SNM) has lobbied to transfer the federal regulation of isotopes used in medicine to the states.

After a two-year review of the NRC's Medical Use Program by the National Academy of Sciences' Institute of Medicine (IOM), the 16-member panel issued a report on December 14, 1995 which removes regulatory authority from the NRC, shifts federal guidance to the Department of Health and Human Services (DHHS) and delegates regulatory responsibility for byproduct material to the states. The draft suggested that state regulations for radiation control should be prepared by the Conference of Radiation Control Program Directors (CRCPD).

The IOM study was requested by the NRC in the wake of a series of newspaper articles that heightened public concerns about radiation risk. Efforts by the NRC's Advisory Committee on Medical Use of Isotopes (ACMUI) also contributed to the study's necessity: the ACMUI committee will use the results of the IOM study to resolve issues of NRC regulation. Although the IOM committee did not argue the NRC's ability to ensure safety, it did find fault with the agency's regulations that hinder efficiency and raise costs in the practice of medicine.

If implemented, the IOM proposal would affect nearly 50 radionuclides that are currently used in medicine and biomedical research. The IOM panel said that the Food and Drug Administration should still regulate the safety of radiopharmaceuticals, the Environmental Protection Agency should continue to set radiation standards and the NRC should continue to regulate radiation doses to workers and members of the public.

The panel's recommendations make sense to medical practitioners such as radiologist and longstanding SNM member Barry Siegel, MD, of Washington Uni-

versity in St. Louis, MO. "We need regulation of nuclear medicine, but the people that regulate nuclear power plants are not the people for the job," Siegel said.

The College and Society's Role

The American College of Nuclear Physicians (ACNP)/SNM Government Relations Office has been lobbying to transfer the NRC's authority to the states. "Regardless of the NRC's decision on the IOM report, congressional relief will probably be necessary before this is resolved," said David Nichols, Associate Director of the ACNP/SNM Government Relations Office.

Nuclear medicine physicians have argued that the states should expand their existing radiation safety control programs to include the regulation of nuclear reactor byproduct materials, which constitute only approximately 10% of all ionizing radiation used in medicine today. Currently, all other forms of ionizing radiation used in medicine are regulated by the states, including the use of x-ray machines and particle accelerators.

While the IOM report is currently under review by the NRC, the ACNP/SNM Government Relations Office is actively seeking to dissolve the NRC's Medical Use Program. SNM, President, Peter T. Kirchner, MD and ACNP President David R. Brill, MD, along with other members of the ACNP/SNM leadership, met with NRC's current chairman, Shirley Ann Jackson, PhD as well as Commissioners Kenneth C. Rogers and Greta Dicus on February 16th to discuss the report's recommendations. A detailed report on the outcome of the meeting will be published in a future issue of *SourceLine*.

If Jackson decides to alter the NRC's current role of regulating the use of medical isotopes, her decision will be consistent with former NRC Chairman, Ivan Selin and former Commissioner E. Gail de Planque, who advocated ending the NRC's Medical Use Program before they stepped down this past year. "Although the NRC has provided a safe environment for both patients and administrators, the

states have also shown their ability to protect patient safety in regulating the use of radiation," said IOM Committee Chair Charles E. Putman, who serves as Professor of Radiology and Medicine and Senior Vice-President of Duke University, Durham, NC, in a recent press release. This option would sustain the high level of patient and worker safety, reduce duplicative regulation and foster a better allocation of resources, Putman said.

Ultimately, the study holds, if the NRC's authority to regulate the medical use of radioisotopes continues, patients will not receive the procedures they need in a cost-effective manner. Fewer people will benefit if regulation makes radiation medicine expensive and therefore less accessible to patients because fewer institutions cannot afford to offer these procedures.

Transfer of Authority

The transfer of authority from the NRC to the states will occur only after the Secretary of Health and Human Services has implemented a system to assist the states in setting up their own enforcement mechanisms. The IOM panel said the DHHS should also monitor the effects of deregulation and enhance the training and standards for health care.

—Stacey Silver

The final slate of candidates for the 1996 SNM Election:

Vice President-Elect Candidates:

James W. Fletcher, MD
Conrad Nagle, MD

Delegates-At-Large Candidates:

Ralph Blumhardt, MD
David R. Brill, MD
Brian Eisenberg, MD
Bennett S. Greenspan, MD
Mark T. Madsen, PhD
Tom R. Miller, MD, PhD
Martin P. Sandler, MD
Mathew Thakur, PhD
Jack A. Ziffer, MD, PhD

Elected Chapter Delegates:

J. Randolph Perry, MD, Southeastern Chapter
Michael A. Wilson, MD, Central Chapter
Harvey Zeissman, MD, Mideastern Chapter