NEWS BRIEFS

Federal Rad Waste Act Upheld

A federal court of appeals unequivocally dismissed all challenges to the Low-Level Radioactive Waste Policy Amendments Act brought by the state of New York against the federal government. The August 8 ruling of the Second Circuit Court of Appeals affirms a U.S. district court decision that the act does not violate state sovereignty as protected under the Constitution.

The ruling comes as good news to nuclear medicine and other users of radioactive material across the country who have closely followed New York's legal opposition to building waste disposal sites. The Society of Nuclear Medicine, the American College of Nuclear Physicians, and ten companies had filed *amicus curiae* briefs on the side of the federal government.

The New York attorney general's office has said the state will appeal the decision and the Ohio and Texas attorneys general are expected to file *amicus curiae* briefs on behalf of New York. If New York files an appeal, then the case will go before the Supreme Court, which has the option to review the case or reject it.

The 1985 congressional act contested by New York set deadlines for go-alone states and regional compacts to build disposal sites for low-level radioactive waste. The act imposed penalties for noncompliance, including a controversial provision requiring states to take possession of waste—and assume liability for damages incurred—as a consequence of failing to meet deadlines for establishing waste handling sites.

In February 1990, New York and two counties in the state joined in litigation claiming that provisions of the 1985 amendment violated constitutional guarantees of states' rights. The U.S. District Court in Albany dismissed the suit the following December.

In upholding that decision, the appeals court judges wrote that "the Low-Level Radioactive Waste Policy Amendments Act of 1985. . .was not an impermissible affront to state sovereign immunity protected under the Tenth Amendment" and like the district court they found no Eleventh Amendment violation and dismissed all remaining challenges. ■

Misadministration Data Released

The rate of misadministrations of diagnostic nuclear medicine over the last ten years in the U.S. amounted to only about 1 per 10,000 procedures performed, according to figures in the 1990 Annual Report of the Nuclear Regulatory Commission, which was released in September.

U.S. Physicians performed about seven million diagnostic nuclear medicine tests and 180,000 therapeutic procedures in 1990. Medical licensees reported 443 diagnostic misadministrations to the NRC in 1990, about 10% more than the previous year. Licensees reported 24 therapy misadministrations, more than twice the number in 1989. These figures include only misadministrations by medical users of radioactive isotopes in the 21 states licensed by the NRC.

The NRC estimates that 40% of all nuclear medicine tests are carried out by licensees in the NRC-regulated states, and the rest by physicians licensed by the state governments in the 29 agreement states.

The NRC defines a "misadministration" as any of the following events:

- A radiopharmaceutical or radiation given to the wrong patient, or by a route of administration not intended by the prescribing physician, or from a sealed source other than the one intended.
- A diagnostic dosage of a radiopharmaceutical more than 50% different from the prescribed dosage.
- A therapeutic dosage of a radiopharmaceutical varying by more than 10% from the prescribed dosage, or different from the final prescribed total treatment dose from a sealed source by more than 10%.

The risks posed by misadministrations in nuclear medicine are "very low," according to the National Council on Radiation Protection and Measurements (NCRP). In a report prepared for the NRC, the NCRP calculates the risk of a fatal cancer to be no more than 1 per 11,000 misadminstrations. This estimate assumes that each misadministration necessitates an extra test, which is usually the case—last year 71% of diagnostic nuclear medicine misadministrations resulted from accidental substitution of the wrong pharmaceutical, and 23% involved the radiopharmaceutical being given to the wrong patient. ■

Error Rate for Misadministrations (Based on aggregated 10-year data)

Type of Procedure	Estimated No. of Procedures by NRC Licensees	No. of Misadministrations	No. of Patients	Error Rate
Therapy				
Teletherapy	368,000	50	122	0.0003
Brachytherapy	184,000	30	30	0.0002
Radiopharmaceutical	115,000	18	18	0.0001
Diagnostic	38,000,000	4,066	4,715	0.0001

U.S. Nuclear Regulatory Commission

News Briefs

BRC Consensus Effort Proceeding

Nuclear physician Stanley J. Goldsmith, MD, will represent the biomedical community in the Nuclear Regulatory Commission's consensus building effort to redefine the "below regulatory concern" (BRC) policy for regulating low-level radioactive waste, which the commission withdrew in July.

Dr. Goldsmith, of the department of physics and nuclear medicine at Mt. Sinai Medical Center in New York City, will join a small core group orchestrating the consensus process and slated to meet formally on October 31.

The NRC proposed the BRC policy over a year ago, intending to define levels of radiation in waste and recyclables that do not require stringent regulation. Environmental and consumer groups responded with strident criticism of the regulators, and some states introduced legislation to overrule the policy with strict rules for disposal.

To salvage the policy, the NRC invited representatives of biomedical research, nuclear medicine, pharmaceutical industry, public interest, and environmental groups to participate in the consensus-building process. Members of the core group will include Environmental Protection Agency Administrator William Reilly, NRC Commissioner Kenneth C. Rogers, two state governors, an environmental representative, and Dr. Goldsmith, the medical representative.

Dr. Goldsmith characterized the NRC's aim as a good-faith effort to hammer out an agreement on the BRC policy. "The NRC recognizes the existence of mistrust of government, and is giving control of the [BRC consensus] process to interested groups, including environmentalists," he said.

"My impression is that Commissioner Rogers is eager to dispel distrust of the NRC," said Dr. Goldsmith after meeting with the commissioner in September.

With the escalating costs of low-level radioactive waste disposal, and reduced access to disposal sites, national standards for regulating low-level radioactive waste are attractive to biomedical users of radioactive isotopes. Hospitals and research institutions are currently dealing with the low-level radioactive waste disposal crisis by building and enlarging holding areas to contain material until its activity decays. The increasing burdens, says Dr. Goldsmith, "are distracting physicians from their primary mission."

Biomedical researchers and nuclear physicians have backed the concept of the BRC policy, believing that a national standard would help hold down the costs and facilitate the disposal of low-level radioactive waste. "It's conceivable," says Dr. Goldsmith, "that the obstruction of the NRC effort to develop a coherent national policy could result in the creation, state by state, of regulations that make storage [of radioactive wastes on-site] a tremendous burden on hospitals without any gain in safety." ■

Maneuvering Against NRC Fees

The Society of Nuclear Medicine and the American College of Nuclear Physicians have petitioned a federal court to review the Nuclear Regulatory Commission's drastically increased user fees, which the medical societies say will erode public access to nuclear medicine services by forcing some hospitals and clinics to discontinue programs.

The petition was filed in the federal court of appeals for the District of Columbia on August 30, in parallel with one opposing the NRC's quality management rule. The aim of both petitions is to open negotiations with the NRC without closing the door on further legal options, according to SNM and ACNP legal counsel.

Congress passed legislation in 1990 that requires the NRC to fund itself entirely from fees charged to licensees during fiscal years 1991 to 1995. The NRC published a final schedule in July. Average fees per user in fiscal 1991 are at least six times greater than in 1990, according to SNM and ACNP calculations. Although the NRC granted a maximum level of $1800 per year for small licensees, charges to some of these licensees still amounted to triple the 1990 rate.

The effects of the fee hikes have already had an impact on nuclear medicine. As of this writing, the NRC has processed 43 requests to terminate medical licenses since the user fees took effect in July, and these former licencees will no longer provide nuclear medicine procedures. Of the remaining 2,307 medical licensees, at least another 81 have filed to have their licenses dropped. SNM and ACNP leaders are concerned that more of the NRC medical licensees will bail out under the burden of the new fee schedule, particularly private clinics and small, rural hospitals. ■

Fast Growth for U.S. Immunoconjugates Market

Although radiolabeled monoclonal antibodies still await FDA approval for clinical use in the United States, the anticipated demand for immunoconjugates for treatment and detection of cancer is expected to give rise to a multibillion dollar market in as few as five years, according to a recently released market survey.

U.S. sales of monoclonal antibody conjugates, which totaled about $93 million in 1991, will surge to $2.34 billion by 1998 and constitute nearly half of the total market for immunotherapy agents, according to the projections of Frost & Sullivan, Inc., New York, New York. The firm expects most of the growth to occur over the next four years. The report notes that the U.S. monoclonal antibody market was virtually zero prior to 1991. ■