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NRC in Disarray over Report of Teletherapy Deaths

Prompted by newspaper disclosures of lethal radiotherapy overdoses that went unreported to federal authorities, the chairman of the U.S. Nuclear Regulatory Commission said it would reform and tighten oversight of the medical use of radioactive materials.

A series of articles in the *Cleveland Plain Dealer* in December presented evidence of 40 deaths since 1975 resulting from teletherapy overdoses, none of which were reported to the NRC because the treatments were performed in self-regulated agreement states or with linear accelerators or x-ray devices not subject to NRC control. The newspaper charged that state and federal regulators have failed through mismanagement and laxity to respond adequately to errors in diagnostic and therapeutic radiation treatments. The newspaper also reported isolated cases in which hospital officials tried to cover up misadministrations, and in which physicians implicated in criminal conduct avoided disciplinary measures.

Among other advocated changes, Chairman Ivan Selin, PhD said in an interview with the *New York Times* that the NRC would follow up each case of overexposure and tell the patient the extent of the problem. The *Plain Dealer* had criticized the NRC for allegedly keeping information from patients and their survivors. Dr. Selin said that the commission would track the rate of errors in radiation administration and that the commission will appoint a panel of outside experts to review its work. Since the NRC already tracks misadministrations and appoints an outside panel of experts, the Advisory Committee for the Medical Use of Isotopes, the meaning of Dr. Selin's comments is unclear. Only a year ago, the NRC concluded a lengthy process of revising the definition of misadministrations in such a way that frees

physicians from reporting many errors involving diagnostic radiopharmaceuticals and some errors involving radiotherapy. The new definitions became effective in January 1992.

When asked for specifics about Dr. Selin's intentions, NRC's Richard E. Cunningham, director of industrial and medical nuclear safety, declined to comment to *Newsline*. "I don't know where Dr. Selin got his information so I have no comment," he said. "I have not had a chance to discuss the matter with the chairman," he remarked in a brief telephone interview 3 days after the chairman's statements appeared.

Dr. Selin said the newspaper articles revealed information that may have been known by staff members, but claimed that it was never assembled and brought to the attention of the five commissioners. NRC staff prepare quarterly and annual reports summarizing misadministration data for NRC-regulated states and recently began doing so for agreement states.

The overall error rate for nuclear medicine and teletherapy misadministrations remained "very low" in 1991, according to the latest annual report to Congress from NRC.

About 2 out of 10,000 radiopharmaceutical therapy administrations result in error, 3 out of 10,000 teletherapy procedures, and 1 out of 10,000 diagnostic radionuclide scans, by NRC estimates. U.S. physicians perform more than 7 million diagnostic nuclear medicine procedures and 30,000 radiopharmaceutical therapy procedures annually. NRC licensees conduct about 40% of these treatments and physicians licensed by agreement states account for the remaining 60%. The National Council on Radiation Protection and Measurements estimates the total national misadministration rate at 1,400 per year.

NRC licensees reported 444 diagnostic misadministrations involving 489 patients in 1991. The risks posed by errors in radiopharmaceutical administration are slight, according to the NCRP. In a report written in 1991, the

NCRP calculates that the theoretical risk of a fatal cancer to be no more than 1 per 11,000 misadministrations, assuming that each error necessitates an extra test.

Of the 19 therapy misadministrations reported by NRC licensees in 1991, 5 involved radiopharmaceuticals and the rest were teletherapy and brachytherapy errors.

Among the 21 NRC-regulated states, the number of therapy misadministrations reported in 1991 is comparable to 1990 figures, but about twice the annual average over 1981-89.

Only 16 of the 29 agreement states submitted misadministration reports to the NRC in 1991, the first year in which federal officials evaluated data from agreement states. These licensees reported 6 therapy and 112 diagnostic misadministrations.

The news articles criticized misadministration records because some serious radiation therapy injuries escaped the NRC's attention. Federal laws don't require hospitals to report therapeutic overdoses if the total dose doesn't exceed the prescribed dose by more than 20%, even if the prescribed dose is at odds with recognized standards of care. Other errors went unreported to federal regulators because the NRC only recently began requiring misadministration reports from the 29 agreement states. The use of x-ray machines and linear accelerators in medicine has never been regulated by the NRC.

Rep. Mike Synar of Oklahoma and Sen. John Glenn of Ohio have tentatively scheduled separate congressional hearings to probe the NRC's management of nuclear safety in medicine. ■

Nuclear Physician Joins AHCPR Cancer Pain Panel

The Agency for Health Care Policy Research has appointed nuclear medicine physician Edward B. Silberstein, MD to its panel developing guidelines on cancer pain management. The AHCPR is a federal agency under the U.S. Public Health Service responsible for facilitating the development of clinical practice

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guidelines, which are expected to influence medical technology assessment and reimbursement decisions.

Dr. Silberstein is a professor of radiology and medicine at the University of Cincinnati Medical Center and director of the nuclear medicine service at the Jewish Hospital of Cincinnati, Ohio. He and colleagues in Cincinnati have investigated the use of phosphorus-32 and promising new radionuclide therapies for diminishing the agonizing pain of cancer that has metastasized to the skeleton.

The U.S. Food and Drug Administration has cleared ³²P for marketing. Clinical trials with strontium-89 have concluded and FDA approval is imminent, while trials with rhenium-186-diphosphonate and samarium-153-EDTMP are underway.

"These are major advances in our ability to treat patients," says Dr. Silberstein, who will be among physicians leading a continuing education session on managing bone pain at the SNM Annual Meeting in Toronto. A considerable amount of literature already documents how radionuclide therapy agents can significantly reduce pain in patients with metastatic bone cancer. But Dr. Silberstein comments that the nuclear medicine literature "must be recognized as important by the larger group of our medical colleagues. Radiotherapists don't know much about what we do."

The AHCPR panel is working on an eighth draft of recommendations for managing the pain of cancer patients. The oncologists, anesthesiologists, nurses and other specialists on the panel had not considered the palliative radionuclide therapies in earlier drafts. The American College of Nuclear Physicians and The Society of Nuclear Medicine nominated Dr. Silberstein for the panel last summer and the AHCPR approved his appointment in November.

"The issue before us is what degree nuclear medicine and radiopharmaceuti-

cals will be included in developing descriptions of appropriate ways of treating bone pain," says Dr. Silberstein. "These panels are going to write the policies that either include us or exclude us." ■

On Causation Between Radiation and Cancer

How definitively can science say whether someone's previous radiation exposure caused later development of cancer? Weighing in on a question fraught with legal implications for all industries that use radioactivity, the National Council on Radiation Protection and Measurements recently published a brief statement outlining just what can and can not be confirmed about cancer causation.

Ionizing radiation leaves no known tell-tale mark on cells that become cancerous. "As a result, it is not possible, on the basis of medical evaluation, to unequivocally prove or disprove a claim that a specific malignancy was caused by a specified radiation exposure," according to the authors of NCRP Statement No. 7, *The Probability That a Particular Malignancy May have Been Caused by a Specified Irradiation*. The only exceptions cited are a malignant hemangioma of the liver following thorotrast injection and a mastoid carcinoma following ingestion of radon precursors. The NCRP is a nonprofit scientific association often contracted to advise government agencies.

The four-page statement advocates probability of causation as the best available means for establishing whether a radiation exposure is related to later development of cancer. The authors briefly describe the use of risk coefficients derived from epidemiological studies of populations exposed to radiation to arrive at a conditional probability that an individual's cancer resulted from a particular radiation exposure.

Probability of causation is a "logical procedure" for responding to ques-

tions for which science has no absolute solutions, the authors say. Estimates of individual radiation dose, if available, can be plugged into a formula to determine probability of causation. The approach offers a quantitative means for evaluating the causation of cancer in radiation-exposed groups or for ranking individuals in a group for the relative likelihood that their malignancies were radiation induced.

Probabilistic methods are obviously limited by the fact that they apply epidemiologic data to individuals, which entails the assumption that each individual is of average susceptibility. The NCRP authors note, however, that probability can be tailored to individuals by age, sex, type of malignancy, and other factors.

"Someday we will probably be able to identify molecular markers that will say where a particular cancer came from," says William Beckner, NCRP senior staff scientist. "All the Council is saying is until then this is the best science can do."

Copies of NCRP Statement No. 7 are available free from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814, telephone: 800-229-2652. ■

ABNM Certification Candidates Up in 1992

In 1992, a total of 120 candidates for certification by the American Board of Nuclear Medicine took the ABNM certifying examination—a slight increase over the previous year's 116 candidates and the largest number to sit for the exams since 1981.

Of the current crop, 57 graduated from U.S. medical schools, 7 from Canadian schools, and 55 from medical school in other countries. The majority of the candidates were certified by the American Board of Internal Medicine, as was the case in 3 of the previous 4 years.

The ABNM, headquartered in Los

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Angeles, California, has awarded about 80 certificates a year for the past ten years. About 75% of candidates pass the examination. ■

VA Hospital Says Nuclear Medicine Halt is Hearsay

The Veteran's Administration Medical Center in Ann Arbor, Michigan is displeased with all the attention it's getting from reports that waste disposal problems have halted nuclear medicine at the institution.

"We're not curtailing anything," says Milton Gross, MD, chief of nuclear medicine at the Ann Arbor VA. "If anything, our service continues to expand."

But various accounts that have cropped up even in national newspapers say the hospital is turning away nuclear medicine patients. A recent front-page story in *the New York Times* about radioactive waste disposal claims that after Michigan was expelled from the Midwest Low-Level Radioactive Waste Compact, the Ann Arbor VA hospital, "among others, sends patients out of state if they need radioactive materials for diagnosis or treatment."

Officials at the Ann Arbor VA dismiss the story as a rumor that defies common sense, and say that none of the papers that made the claim bothered to check its accuracy with the VA. The short-lived isotopes used in clinical nuclear medicine can be decayed safely on hospital premises and then sent out with other medical trash for burial or incineration, so clinical departments typically have minor waste disposal problems compared to biomedical research laboratories.

The industry newsletter *Straight Talk* is probably the first to print the claim about the Ann Arbor VA and is the apparent source of subsequent printed accounts. The newsletter contends in its November issue that the VA hospital is "no longer accepting patients requiring diagnoses and treatments that utilize

radioactive materials," that such patients "are being referred to other hospitals outside the state," and that research programs "have been put on hold." The newsletter is produced by Cal Rad Forum, a California-based association for industries that produce radioactive waste.

The VA's Dr. Gross says the nuclear medicine department at the Ann Arbor facility treats 4,000 patients a year, and the hospital employs about 40 researchers with an annual budget over \$3.5 million. The only "hold" placed on researchers, according to Dr. Gross, is the request that they shift to shorter-lived isotopes when possible. The radiation safety officer at the Ann Arbor VA, Joe Wissing, says he had to designate additional storage space in a basement for holding drums of low-level waste for decay or eventual burial when a disposal site opens. He estimates the VA has enough space to last at least 5 and perhaps 10 years before research is seriously threatened. The failure, however, to build disposal sites in the U.S. is creating a looming crisis. Eventually, Mr. Wissing says, "the waste is going to have to go somewhere."

The author of the newsletter story, Nicki Hobson of Cal Rad, told *Newsline* that she stands by her claim that the VA is halting nuclear medicine services. Ms. Hobson declined to identify who gave her the story and acknowledges that she didn't call the VA to verify it, but says she checked back with the source when people started questioning the report. As to Dr. Gross's assertions that her story is "totally false," she responds that "if a hospital can't provide full services, I can see why he would try to put the best face on the situation."

The VA's Dr. Gross claims it's a case of not letting the facts get in the way of a good story. "This is just the kind of sensational information that a compact would want," he says, as evidence to support the nuclear industry's need for low-level waste repositories. To those who've claimed the VA is halting nuclear medicine services he says, "come and audit our books." ■

Hospital Waste

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according to Mr. Gantner. "The last thing we want to do," he says, "is burn a significant source in a medical waste incinerator."

Some state radiation control programs encourage waste handlers to set detectors as sensitive as possible. "Otherwise stuff that's shielded can get through, then you might miss something that's been shipped illegally," says Richard Ratliff, director of compliance and inspection at the Texas Bureau of Radiation Control.

Regulatory vigilance, however, is not overburdening hospitals in Texas. The Texas Department of Health adopted a BRC-type rule in 1987 that allows industries to route to ordinary landfills limited concentrations of radionuclides if the half-life is less than 300 days. Licensees must demonstrate the ability to separate the waste, account for concentrations of radioactivity, and properly package it to gain a permit for BRC disposal.

The policy lets hospitals promptly move radioactive medical waste out of hospital storage closets and into a landfill, "where it's safer," says Mr. Ratliff.

One Texas university saved about \$15,000 on waste disposal during the first year of the policy, according to state officials. Another licensee calculated that radioactive material that cost about \$1800 to bury at a municipal landfill would have cost over \$38,000 to ship to one of the low-level radioactive waste repositories in 1991.

Nuclear medicine physicians point to the Texas policy as evidence of the need for national standards. Many are coming to the conclusion that they will have to negotiate with landfill operators and local communities to establish allowable levels of radiation that all can accept.

"If and when the NRC comes out with a BRC rule, we can set our systems to a higher threshold," says BFI's Mr. Gantner. "Until the NRC comes out with a BRC rule, this is what we have to live with."

J. Rojas-Burke