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Court Upholds Nuclear Quality Management Rule

The U.S. Court of Appeals for the District of Columbia denied a petition filed by The Society of Nuclear Medicine and the American College of Nuclear Physicians asking the court to void the Quality Management Program, a rule the U.S. Nuclear Regulatory Commission made final in January 1992.

In an expedited decision on the disputed rule issued on May 22, ten days after hearing oral arguments, the presiding circuit judges wrote that "The NRC, in promulgating the QM Rule, acted within the bounds of its broad statutory mandate" to establish standards that the NRC deems necessary to protect health or to minimize dangers. The judges further ruled that the requirements of the Quality Management Program are neither "arbitrary, capricious, [nor] an abuse of discretion," as argued by SNM and ACNP.

SNM and ACNP maintain that the new regulations intrude into the practice of medicine and duplicate existing quality assurance measures. The organizations claim that the rules will inflate the costs of medical care while doing little, if anything, to improve an "already irreducibly low" rate of misadministrations (see *Newsline*, May 1992, p. 37N).

During May 12 court proceedings that lasted less than an hour, Presiding Judge Harry T. Edwards aired his belief that the nuclear medicine societies' dispute with the NRC was a matter for Congress to decide and that it was not the court's duty to evaluate costs and benefits nor to question NRC's authority to regulate nuclear licensees. SNM and ACNP attorney Sheldon Trubatch maintained that it was up to the court to determine whether the NRC abused its authority by not fully assessing the need for the new regulations.

Quoting NRC Chairman Ivan Selin, Roger Davis of the NRC Solicitor's Office said that the Quality Management Program would be appropriate

even if it were to prevent only one medical error. Judge James L. Buckley and Judge David B. Sentelle, apparently disagreeing, asked how the NRC could justify the new rules—described by Judge Sentelle as a "regulatory morass"—if they would prevent perhaps fewer than one wrongful treatment out of millions performed every year.

Judges Buckley and Sentelle asked Mr. Davis if the NRC had compared the safeguards employed by nuclear medicine to those of other medical specialties and if in drafting the quality management rules the NRC had considered existing state laws for the practice of medicine. They also pressed the NRC attorney for details on the health consequences of nuclear medicine misadministrations. In the end, the judges found no basis to overturn the Quality Management Program.

With the court's decision, SNM and ACNP representatives say the societies will probably try to negotiate with the NRC to limit intrusion into the practice of medicine. At press time, members of SNM's committee on government relations were mulling the option of asking Congress to clarify the NRC's role in the regulation of medical uses of isotopes. In a memo to ACNP and SNM leadership, government relations director Kristin Morris says that "as an independent agency, NRC is not bound by any of the checks and balances placed on other regulatory bodies," and that "Congress has all but relinquished its oversight authority since NRC's appropriations are funded through user fees." She adds that "Until Congress is convinced of the need to define NRC's broad mandate, nuclear medicine will be at risk of being sacrificed by the agency in an effort to appease the relentless critics of nuclear power."

Earlier in May, a group of state nuclear regulators that has opposed the Quality Management Program held off making any recommendations for state rules for compliance with the NRC, pending a

decision from the appeals court. The Conference of Radiation Control Program Directors, which represents both NRC-regulated states and the agreement states with radiation control programs compatible with the NRC, met in Orlando, Florida in May and the committee responsible for reviewing and recommending changes for agreement state regulations for nuclear materials declined to consider the NRC's Quality Management Program. ■

Myth Making at Hanford

Using the often repeated swords-into-ploughshares theme, a number of recent media reports have drawn attention to the peaceful uses of by-products of nuclear weapons production at the Department of Energy's Hanford site in Washington. The February 28 issue of *Science*, for example, announced that a shipment of cesium-137 recently left Hanford bound for "hospitals and labs around North America" through a deal with Nordion International of Canada, which uses ¹³⁷Cs to make industrial irradiators, which among other things are used to sterilize blood. The April Health Physics Society Newsletter reported that the "nuclear wastes" would be "used for life-saving medical applications."

The media reports all create the impression that culling these particular nuclear "wastes" for useful products is something new, when in fact, for well over a decade, the U.S. government has marketed a multitude of useful isotopes separated during the production of plutonium for nuclear weapons. The separated isotopes, far from being waste material, have been stored in sealed canisters at Hanford awaiting commercial and research applications.

Nordion itself has obtained ¹³⁷Cs from Hanford stockpiles for about 15 years. Yttrium-90, which has been used in clinical trials as an agent attached to monoclonal antibodies for cancer therapy, and

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strontium-90, which has been used with success to alleviate painful bone metastases, both come from the byproduct stream from plutonium production by the DOE. Over the past two years DOE has transferred radioisotope production and distribution work formerly conducted at the Oak Ridge National Laboratory in Tennessee to Hanford, where hot cells and other assets have been consolidated.

Behind all the recent media accounts is a press release from Westinghouse Hanford Co. and Battelle's Pacific Northwest Laboratory, the companies that run Hanford. The press release appears to be an attempt to use the occasion of resumed ^{137}Cs sales to generate favorable publicity for the extensive restoration and waste management work underway at Hanford, where soil and ground water at thousands of locations is contaminated with a range of chemicals and radionuclides deposited since the beginning of the nuclear arms race.

The Energy Department's publication *DOE This Month* stated in March that isotope production and processing is now "part of Hanford's new environmental restoration and waste management mission," without noting that the isotope production activities began years ago. Taking its cue from the DOE, *Science* magazine called the ^{137}Cs transaction "part of DOE's massive program for combining the cleanup of high-level radioactive waste with its commercialization." ■

Radionuclide Production Threatened in Poland

Poland dissolved its Institute of Atomic Energy on April 1 of this year, leaving uncertain the fate of a pair of important research reactors at the Swierk research center near Warsaw. Shutdown of the reactors would deprive Poland of its only domestic source of radioisotopes for nuclear medicine, scientific research, and other uses.

According to a report published in *Nuclear News* (May 1992), former paid employees of the Institute are voluntarily keeping watch over the reactors, named Ewa and Maria, and the pool in which radioactive fuel from both reactors is stored.

Since breaking away from the erstwhile Soviet Union, the Polish government has taken an aggressive anti-nuclear stance. Officials canceled construction of a partly built nuclear power plant at Zarnowiec and following a series of severe budget cuts imposed by the government's Scientific Research Committee, the Institute of Atomic Energy was forced to disband. ■

JNM Seeking New Editor

The Journal of Nuclear Medicine's editor-in-chief, H. William Strauss, MD, is leaving his position at Massachusetts General Hospital in Boston to work for E.R. Squibb & Sons, Inc. of Princeton, New Jersey. The responsibilities of the new position preclude Dr. Strauss from completing his full five-year term as editor.

The Society of Nuclear Medicine's Publications Committee has accepted letters of intent from individuals interested in being considered for the editorship of the Journal. The committee is now evaluating candidates.

A tentative timetable would have an editor nominated for a five-year term by the end of 1992, with editorial duties commencing February 1993. Dr. Strauss will remain editor-in-chief until a new editor is elected and ready to begin working. ■

Perceptions of Radiation Risk

A nationwide survey of popular feelings about radiation in the U.S. has shed light on the unexpected ways people react when experts try to quell unwarranted fear of nuclear technology.

Some commonly used statements intended to assuage fear actually backfired and aroused greater concern, according to an analysis of the poll recently published by the U.S. Council for Energy Awareness (USCEA), the public relations arm of the nuclear power industry.

Contracted by USCEA, the Gallup Organization interviewed 1,020 adults in January and February of 1991. Among other things, interviewers asked subjects to select the two most reassuring and the two least reassuring of 15 factual statements about radiation.

To convey a sense of relative risk, scientists often compare radiation levels from nuclear energy to natural sources, such as solar radiation or granite in buildings. Rather than putting risk into perspective as intended, however, these statements alarmed a significant number of respondents, making them fearful of dangers around them that they hadn't known existed. Other respondents worried that radiation produced technologically was somehow more harmful than that existing in nature.

Although no single statement reassured everyone, qualitative statements about control over radiation were more convincing than quantitative comparisons of natural radiation and artificially produced radiation.

The most reassuring statements were reminders of the beneficial uses of radiation—especially medical applications—probably because such concrete examples demonstrate control or "technological harnessing of radiation," in the words of the authors of the report, Ann S. Bisconti, PhD and Robert L. Livingston. "If the monster is not demystified, the second-best hope is to control it," the authors write.

Advising people that radiation from nuclear plants is constantly monitored to meet strict standards enforced by federal regulators was the next most reassuring statement, followed by the point that radiation is well understood by scientists and easily detected and measured.

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The survey also showed that attempts by scientists to inform the public about radiation risk are in competition with impressions from the popular media. Large majorities of Americans reported learning about radiation from news coverage as well as dramatic episodes from T.V. and film. Some 13% even reported getting information or impressions on the subject from cartoons and comic books. ■

E&R FOUNDATION STUDENT FELLOWSHIPS, APRIL 1992

The Education and Research Foundation of The Society of Nuclear Medicine in April awarded fellowships of \$3,000 to the following graduate students:

Robert M. Berman, University of Pittsburgh Medical School, PA

Thomas A. Bonasera, MA, Washington University, St. Louis, MO

Thomas M. Guerrero, MS, UCLA School of Medicine, Los Angeles, CA

Donald C. Lien, University of Pennsylvania School of Medicine, PA

Lorie A. Szlacky, University of New Mexico College of Pharmacy, Albuquerque

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dents have been rather uniquely successful."

"His lab was a very lively place with research going in all directions," says another former post-doc in Dr. Welch's lab, Mark A. Green, PhD, associate professor of medicinal chemistry at Purdue University School of Pharmacy, West Lafayette, Indiana. Dr. Green says he had been considering a career as an industrial chemist before he heard of Dr. Welch's work and became intrigued with the idea of chemistry with direct clinical applications. Dr. Welch, he says, opened his eyes to the crucial role of chemists in developing new radiopharmaceuticals. "He really gives people a vision of how to look at problems in nuclear medicine and radiopharmaceutical chemistry," says Dr. Green. "He was always a person I would turn to for advice and direction after I left Washington University."

As a research collaborator, Dr. Welch has compiled an impressive record. "He has established successful collaborations across a variety of disciplines," says William C. Eckelman, PhD, of the National Institutes of Health, a long-time friend of Dr. Welch who presented the Hevesy Award at the SNM Annual Meeting. Dr. Eckelman places the number of Dr. Welch's collaborations within Wash-

ington University at 200, with at least another 50 outside the university.

"He is always on to some new idea that will put new relevance on the work he has done in the past," says Barry Siegel, MD, professor of radiology and medicine at Washington University's Mallinckrodt Institute of Radiology, who has frequently worked with Dr. Welch. "Over the years, he has been involved in many areas where he has had no prior experience, but because a clinician presented him with a problem, he has managed to come up with a solution. Because of his successes, people are constantly hounding him as a resource. He's an incredible resource for Washington University."

One of the more recent contributions often ascribed to Dr. Welch is the development, with J. A. Katzenellenbogen, PhD, and others, of bromine-7 estradiol, which according to Dr. Siegel was the first compound for labeling a human receptor binding site. With estrogen molecules, now labeled with fluorine-18, the researchers including Dr. Welch, Dr. Katzenellenbogen, and Dr. Siegel, have shown how the uptake of these fluoroestrogens can be quantitated in vivo with PET. The compounds hold promise for helping the clinician define which breast cancers are estrogen dependent.

Dr. Welch, born in Stoke-on-Trent, England, received his bachelors and

masters degrees from Cambridge University. He holds appointments as professor of radiology at the Mallinckrodt Institute of Radiology at Washington University School of Medicine and as professor in the chemistry department at Washington University. He became director of the division of radiation sciences at the Mallinckrodt Institute in 1990. A past-president of The Society of Nuclear Medicine, Dr. Welch received SNM's Paul C. Aebersold Award in 1980 and he is a two-time recipient of SNM's Berson-Yalow Award. He has also received the American Chemical Society's St. Louis Award, and the National Award for Nuclear Chemistry.

The Society of Nuclear Medicine established the Nuclear Medicine Pioneer Award in 1960 and changed the title of the award in 1979 in honor of Georg Charles de Hevesy, PhD, DSc, the Hungarian chemist who developed the radio-tracer technique. The president of the SNM chooses the Hevesy Award winner each year based on over-all contributions to the field of nuclear medicine. Leon S. Malmud, MD, chairman and professor of diagnostic imaging at Temple University School of Medicine and immediate past-president of SNM says Dr. Welch's "seminal work in PET radiopharmaceuticals will have an impact on our understanding of human pathophysiology for generations."