Nuclear Regulation: Toward A Balanced Perspective

Series in Cleveland *Plain Dealer* provokes Senate and House hearings; GAO report claims state nonreactor nuclear regulation programs inadequate and faults NRC; NRC scrambles to respond to Senate and House hearings amidst staff upheavals.

IN A POLITICALLY TOUCHY situation that began with a newspaper series in December 1992 in the *Cleveland Plain Dealer*, Congress, the U.S. Nuclear Regulatory Commission (NRC), the Food and Drug Drug Administration (FDA), and a myriad of organizations including the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), have been issuing numbers of statements and reports to address accusations of radiation misadministration. Press inacuracies include the confusion of radiation therapy with nuclear medicine and lack of effective NRC oversight. Members of the nuclear medicine community hope that this heightened coverage will in fact increase public awareness of the intrinsic safety of nuclear medicine procedures and lead to a streamlined, more efficient regulatory process. But the events of the past eight months raise questions about press motives; about whether existing radiation phobia thus fueled can be quelled; about government capacity to respond to calls for improvement without escalating the financial and administrative burdens of regulation on medical facilities; and about the capacity of medical specialties to temper reactions to possibly uninformed reporting and regulatory politics.

Freedom of the Press

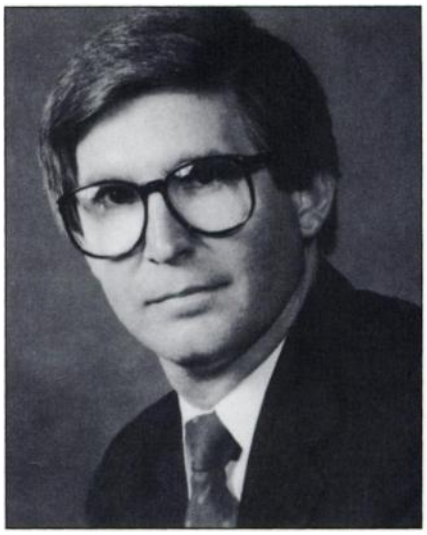
The *Plain Dealer*'s series reported incidents of radiation accidents, injuries and deaths in a fashion which, many observers agree, may dampen public acceptance of nuclear medicine for some time. Many in the field also fear that this type of reporting will cause patients to avoid or delay necessary nuclear medicine tests.

"Public fears have been aroused for purposes other than protecting public safety," says Richard Reba, MD, president of SNM. Unfortunately, whatever damage is done by sensationalist reporting is done initially, according to Conrad Nagle, MD, president of the ACNP; and the press may be unwilling to rectify inaccuracies. When the *Washington Post* picked up one of the *Plain Dealer* stories from the Associated Press wire, it replicated the inaccurate title that linked nuclear medicine with radiation risks. Dr. Nagle wrote the *Post* to request a retraction; the newspaper printed his letter, deeming a letter to the editor sufficient, apparently rather than print a retraction or clarification that would admit press accountability.

The series prompted hearings by committees of the Senate and House, NRC investigations of allegations (reported to the Senate committee), and a report on NRC by the Government Accounting Office (GAO), released in May and reviewed at the House hearing in July.

Congressional Hearings

On May 6, 1993, Senator John Glenn (D-Ohio), chaired a hearing of the Senate Committee on Government Affairs on federal regulation of medical radiation use. Making statements before the committee were Ivan Selin, NRC chairman; D. Bruce Burlington, MD, Director, FDA Center for Devices and Radiological Health; and Aubrey Godwin, Chairman, Conference for Radiation Control Program Directors.



Conrad E. Nagle, MD

After citing the *Plain Dealer* reporters for a commendable job, Glenn quoted statistics on the uses of ionizing radiation—approximately 170 million diagnostic radiation procedures and approximately 20 million radiation therapy procedures annually. He stated that medical radiation regulation is scattered, fragmented, and inconsistent, and focused discussion specifically on those issues.

Selin distinguished between the two categories of radiation medicine use of radioisotopes subject to NRC regulatory jurisdication: use of radioactive drugs containing small quantities of radioactive materials, primarily for diagnosis and mapping of disease, and

radiotherapy. Sealed radiation sources regulated under the Atomic Energy Act (AEA) comprise no more than 25% of radiotherapy treatments, whereas 75% of cases involve radiation produced by electronic devices—including linear accelerators—that do not fall under AEA regulation. He summarized the NRC program, including the agreement state program; addressed jurisdictional issues, including defects in coordination with other agencies, particularly the FDA; addressed the *Plain Dealer* allegations; and described a survey of radiation overdose cases covering the prior three years, in which the NRC found that patients were notified of misadministration in only 72% of cases, and in only 56% of those was written notification given, when specifically required by NRC. Selin indicated that the NRC was exploring long-term "options" for addressing NRC effectiveness issues. Glenn gave NRC exactly three months (no later than August 6) to develop a document.

Burlington summarized the FDA's regulatory program for medical radiation devices, which includes all radiation systems such as medical linear accelerators, cobalt-60 teletherapy units, computerized treatment planning systems, and accessories for radiation treatment therapy. He summarized the scope of the FDA's legislative mandates; described FDA relationships with the NRC and states; and highlighted FDA efforts to decrease the likelihood of adverse incidents involving radiation therapy devices. The latter include issuing user reporting regulations, which require medical facilities to report a device-related death, serious injury, or serious illness; reminding dealers, importers, manufacturers, and distributors about reporting requirements and criteria for reporting; developing a memorandum of agreement with the NRC to cover medical devices using NRC-licensed radiation sources; reassessing the efficacy of notification and communication systems with states; and conducting industrywide inspections of radiation device manufacturers.

Aubrey Godwin addressed the proliferation of ionizing radiation agencies at the federal level of government and the resulting overlap and gaps in enforcement; summarized the legislative history of standardization of use of radioactive materials; and identified areas of concern, including lack of a consistent radiation standard for all medical and industrial users and devices, lack of efficient reporting of problems with ionizing radiation equipment, and inhibition of communications within the regulatory community subject to the Federal Advisory Committee Act.

On July 30, 1993, Representative Mike Synar (D-Oklahoma), chair of the House Subcommittee on Environment, Energy, and Natural Resources, Committee on Government Operations, held a hearing based in large part on the GAO report *Better Criteria and Data Would Help Ensure Safety of Nuclear Materials*. Released in May 1993, the report confirmed that a number of state regulatory programs do not meet minimum NRC requirements. It stated that NRC was unable to certify nuclear regulations programs in Iowa, Nebraska, New Hampshire, New York, and Tennessee, and that eight other states failed to adopt all of NRC's nuclear safety regulations and revisions, including Kansas, Kentucky, Louisiana, Maryland, North Dakota, New Mexico, Texas, and Washington. Despite repeated findings of inadequacy in some state programs, NRC had never initiated action to suspend or terminate a defective state program. GAO criticized the NRC for not having specific criteria or procedures to determine when to suspend or revoke inadequate or incompatible programs; not tracking its own performance in regulating the same types of activities in states in which NRC retains jurisdiction; and not requiring states to report accidents and other indicators of regulatory performance.

The GAO report raised hackles in the nuclear medicine community because the report attributed deaths to nuclear medicine or the administration of nuclear medicine. At the July hearing, the GAO issued a statement retracting the attribution of deaths to nuclear medicine, according to Kristen Morris, ACNP/SNM director of government relations. Both Morris and Nagle emphasized that the issue here and with newspaper reports is whether nuclear medicine is involved, and should not be mistaken as an effort to shift "blame" to another specialty. Morris states that both the Glenn and Synar hearings demonstrated effort to focus on issues and accurately define and interpret problems in regulating uses of ionizing radiation, rather than on medical performance issues; in general, agency testimonies were balanced. *Newsline* contacted the NRC to request interviews on their position. Unfortunately, several individuals involved have been replaced as a consequence of these problems, and *Newsline* was advised that the chairman's statements presented to the Glenn and Synar hearings would have to suffice and could be used for quotes attributed to Selin, but there would be no further comment.

NRC Report on Medical Radiation Protection

On July 28, NRC submitted the document requested by Glenn. It addresses uniformity of requirements and regulatory oversight, database and health and safety implications, training and experience of radiation users and professional personnel, and communication among federal and state agencies; and it proposes five options for allocation of regulatory responsibility. These options are: 1) maintain the current framework for regulating medical ionizing radiation, with the recognition of planned and potential improvements; 2) develop and implement (at the federal level) federal regulations for all sources of ionizing radiation used in medical therapy; 3) develop and implement (at the federal level) regulations for all sources of ion-

(continued on page 32N)

Government Update

(continued from page 29N)

proposed recision of National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Sub Part I. The recision would protect the NRC's sole jurisdiction over the regulation of radionuclide air emissions for material licensees, including nuclear medicine facilities. In 1990, Congress directed EPA to hold the NESHAPs for NRC medical licensees in abeyance pending evaluation of whether licensees were within an ample margin of safety under sole NRC jurisdiction. EPA based its recision proposal on a survey of licensees; the data indicated that NRC licensees operated within EPA standards when complying with NRC regulations. A proposed rule rescinding these NESHAPS was expected in August.

Low-Level Radioactive Waste

▲ California. The California Department of Health Services continues to delay issuing a license for the Ward Valley LLRW disposal facility, though the California State Court of Appeals ruled favorably for the site on May 7. The U.S. Department of Interior's (DOI) Bureau of Land Management also has not set a date to transfer the land, though the DOI was continuing to review the site. The review included an unfavorable report by the DOI's U.S. Geological Survey, which questioned the validity of some environmental impact studies on the area and called for additional studies before land transfer. The site also may be named a critical habitat for the endangered desert tortoise; a suit on behalf of the tortoise is on hold in a California court, pending DOI's identifying the animal's critical habitats.

▲ New York. The New York State Assembly failed to act on a bill that would have designated West Valley as suitable for an LLRW facility. This failure threatens the state's access to South Carolina's Barnwell facility. The Southeast Compact Commission is reviewing New York's status.

▲ Central Interstate Compact. On April 14, the Southeast Compact Commission voted unanimously to terminate its contract with the Central Interstate Radioactive Commission, effective July 1 and affecting Arkansas, Louisiana, Oklahoma, and Kansas. There is currently no plan to reconsider the Central Compact's access to Barnwell.

Kristen D.W. Morris, Director of Government Relations
Valerie A. Fedio, Assistant Director
David C. Nichols, Legislative Assistant
Sandra K. Bilko, Assistant Director of Reimbursement

Nuclear Regulation

(continued from page 18N)

izing radiation used in medical diagnosis and therapy; 4) develop federal regulations for all sources of ionizing radiation used in medical therapy, with the states responsible for implementation; or 5) develop federal regulations for all sources of ionizing radiation used in medical therapy and diagnosis, with the states responsible for implementation.

The Underlying Issues

Efficient, and cost-effective oversight in the use of medical nuclear materials, seemingly a straightforward goal, is hardly a simple concept when one faces a proliferation of agencies and overlap in agency responsibilities; lack of clearly defined overall authority for regulation; lack of standardization in regulations and their implementation from state to state; lack of an integrated information system for collecting and analyzing required data; lack of accountability and quality control of regulatory activities at both federal and state levels; and excessive budgets that call into question the cost benefit of existing agency services. The press's sensationalization of horrifying but isolated incidents of radiation injuries, accidents, and deaths is only the tip of the iceberg.

The reporting has, ironically, paved the way for much-needed examination of the state of affairs of federal and state nuclear regulatory activities and, according to Morris, "has stimulated useful debate that is educating Congress and the staffs of regulatory agencies as well as professional associations and organizations." However, as Nagle points out, "It is essential to proceed cautiously toward the goal of more effective oversight, to prevent insidious escalation of already excessive hidden costs to the health care industry of radiation regulation, to avoid duplication of efforts among agencies, and to forestall the potential to crossover into medical practice purview. To assume the source of underlying problems without careful examination is to potentially identify solutions that may only aggravate the problem." ACNP and SNM have therefore urged that the NRC first obtain an objective study from a separate, scientific organization such as the National Academy of Sciences-Institutes of Medicine before a strategic plan to address perceived problems and before selecting one of the five options NRC outlined in its report to Congress.

"Quality control of uses of ionizing radiation and radiation medical devices through regulation is essential to the safety both of patients and professional staff in medical facilities," Nagle continues. "It must, however, be accomplished in a fashion that balances reasonable cost with reasonable benefit while protecting public safety without jeopardizing the capacity of medical facilities to provide essential services, either because intrinsic costs escalate or because frightened patients decline the services."

Maryanne Shanahan