

COMMENTARY

LINES FROM THE PRESIDENT: DISPELLING THE CONFUSION ABOUT RADIATION SAFETY IN MEDICINE



Paul H. Murphy, PhD

THE REGULATION OF medical radiation safety in the U.S. continues to disappoint both the regulated nuclear medicine professionals and the general public whom the regulations are supposed to protect. Nonsensical and often contradictory policies are to blame.

While nuclear medicine professionals have long criticized the NRC for overzealous oversight and intrusion into the practice of medicine, a series of stories printed in a Cleveland newspaper in December

took the NRC to task for its allegedly lax response to a number of deaths and injuries caused by misadministration of radiation, primarily in teletherapy. Consumer advocates and Congressional watchdogs have been hurling brickbats at the NRC and calling for more stringent oversight of medical applications of radioactive materials ever since.

Unfortunately for nuclear medicine and the patients who benefit from its diagnoses and treatments, the Cleveland *Plain Dealer* added to the confusion surrounding safety in nuclear medicine. The newspaper stories mustered plenty of facts but lost sight of their significance. For example, the reporters referred to nuclear medicine and radiotherapy as if they were one and the same, and although the reporters cited some examples of errors in nuclear medicine therapy with unsealed sources, they failed to make the all-important distinction between the slight risks of errors with diagnostic levels of radioactivity versus the more significant risks of therapeutic levels. Nor did they emphasize the extremely low rate of misadministrations in nuclear medicine and radiation oncology.

To focus on the NRC as the responsible agency for misadministrations in external beam radiation therapy is inappropriate since in today's practice the vast majority of such therapy is accomplished by linear accelerators—which are regulated by the Food and Drug Administration and state radiation control agencies and not by the NRC, which Congress gave authority over only the reactor-produced radioisotopes. The results of this misguided focus on the NRC could well be more stringent regulations that will affect nuclear medicine and not just radiation therapy, exhausting resources better spent on taking care of patients and performing research.

The question remains whether the NRC is trying to walk

the fine line between over and under regulation has failed to uphold its mandate to protect the health and safety of the public. I maintain that existing regulations for nuclear medicine and research using radioactivity are adequate for protecting the public, as is probably the case in radiation therapy. But the global radiation safety program is flawed by inconsistencies.

By virtue of training and our positions in hospitals, medical schools, and clinics, nuclear medicine professionals are often key players in institutional radiation safety programs. We are familiar with the hordes of regulators involved in things nuclear and know well the inconsistencies in emphasis on radiation risks. We worry about the "Notice of Violations" from the NRC or agreement state agencies—and the possible fines—while devoting insufficient time and effort to the much more important but less regulated patient and staff radiation exposures in diagnostic radiology and cardiology. A one millicurie spill of a radionuclide constitutes a significant event evoking more regulatory response than a 60-minute session of fluoroscopy and dozens of films—even though the risks from extended x-ray exposure to the patient and staff are dramatically greater. With examples of such regulatory imprudence, it's no wonder that patients, referring physicians, and legislators perceive the risks of radiation so markedly differently than we do.

Science and medicine use ionizing radiation from reactor-produced isotopes, naturally occurring radioisotopes, or machine-generated high-energy particles and photons. The radiation from all of these sources causes the same thoroughly characterized biological effects, but various sources are controlled by haphazardly inconsistent rules enforced by an assortment of state and federal agencies. Training requirements for users vary from the rigorous standards for NRC-licensed professionals to the non-existent requirements for others who use x-ray equipment, such as cardiologists. A comprehensive training and regulatory framework is needed to add some consistency and logic to the human application of ionizing radiation.

Beating Back Misinformation

Logic and consistency face obstacles, however, in the form of ignorance and misinformation. One proposed NRC policy that would have established uniform national standards for the release of very low-levels of radioactivity from strict disposal requirements has been blocked by Congress. That this much-

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Uranium

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al Atomic Energy Association, a country with demand for 130 Ci or more per week could break even producing its own supply. As more ^{99m}Tc radiopharmaceuticals are developed, demand will only increase.

Advocates of Conversion

Meeting the medical needs of developing countries is one reason the IAEA has supported research on conversion to LEU targets. Nations with growing demand for radiopharmaceuticals but unlikely to secure shipments of HEU would still be able to produce ^{99}Mo domestically if investigators were to come up with alternative designs using LEU. But efforts to equip developing countries for production don't strictly depend on whether industrialized nations convert to LEU targets.

Arms control advocates insist that the threat of proliferation is reason enough to ban exports of HEU and say the sheer volume of the material around the world provides ample support for their cause. Over the years the U.S. has shipped about 24,000 kg of HEU to over 43 countries, primarily in fuel assemblies for research reactors. The 90% enriched fuel remains 40-60% enriched after burning. Most of this spent fuel remains in storage at reactor sites, awaiting shipment to the U.S. in exchange for credits with the Energy Department for more HEU. Only about 6,000 kg have been returned to the U.S. for reprocessing, according to Bas Bruyn, an arms control analyst and consultant to

International Physicians for the Prevention of Nuclear War.

"HEU is a real proliferation concern," says Mr. Bruyn, who believes conversion to LEU targets is necessary "even if it costs a little bit more" to produce radiopharmaceuticals. "The costs of preventing proliferation of nuclear weapons grade materials are also very high," he says.

Slow Process Expected

Despite what appears to be mounting political pressure, the conversion to LEU targets may drag on for years. Prodding the major test reactors to switch to LEU fuels remains a much more pressing goal of the nonproliferation campaign. All eyes are on major facilities like the HFR Reactor at the Petten Establishment in the Netherlands that have yet to convert to LEU fuel, even though trial fuel assemblies are ready and waiting.

If and when viable target alternatives are available, the Schumer amendment allows production facilities to get around the export ban if they can show that conversion to LEU would bring a "large percentage increase" in the total cost of operating the reactor. That won't be an easy task for reactor operators, however, and "the burden of proof is on them," says Mr. Kuperman of Rep. Schumer's staff.

The situation is further complicated by the entry of the Energy Department into the ^{99}Mo market. The department's isotope production program is unlikely to use LEU targets since they recently

bought the rights to HEU target designs used by Cintichem, Inc. a Medi-Physics subsidiary that used to produce isotopes. Furthermore, the Schumer amendment applies no pressure on the DOE to switch to LEU. "Internal use is not a problem, it's not the focus of the legislation," says Mr. Kuperman. Given this scenario, corporations outside the U.S. are likely to resist converting, citing the "bad" example of the Energy Department and its unfair competitive advantage.

Still, arms control officials believe that conversion to LEU targets and fuel is inevitable. "I think so," says Dr. Travelli of Argonne. The only real threat to that outcome he foresees is the expansion of another source of HEU, perhaps one of the cash-starved states of the former Soviet Union. The U.S. has an agreement with the Russian Federation to buy up weapons-grade uranium from the former Soviet Union and convert it into fuel for American nuclear power plants, but estimates of how much of the material the Soviet government had stockpiled and where it is now remain uncertain. China and France are also capable of enriching uranium (France and Russia even supplied 12.3 kg of 93% enriched ^{235}U and 10 kg of 80% enriched ^{235}U to Iraq before the Gulf War). For the Schumer amendment to work as intended, the U.S. would have to convince these foreign governments to clamp down on the distribution of HEU.

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Lines from the President

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needed "below regulatory concern" policy, or BRC, went down in flames when it encountered outraged and fearful environmental activists, consumer groups, and legislators illustrates the profound lack of understanding of risk magnitudes. Whether one is for or against nuclear power utilities, which stand to benefit substantially from BRC, medicine and research desperately need the logical definition of levels of radioactivity that are BRC. We in medicine should take advantage of the opportunity to assist the NRC as the "good guys"

in trying to reduce the costs of health care and regulatory burdens in biomedical research.

Finding the appropriate regulatory balance between cost-effective, acceptable risk constraints and overburdensome, stifling restrictions is never easy or given to unanimous agreement. But the lack of a comprehensive and consistent program for all ionizing radiation satisfies no one, and is at the core of the NRC's and radiation medicine's current dilemma.

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President*