

American  
College of  
Nuclear  
Physicians

The Society  
of Nuclear  
Medicine

November 1, 1989

The Honorable Kenneth M. Carr  
Chairman  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555

Dear Mr. Chairman:

It was certainly a pleasure meeting you and your staff recently to discuss the Nuclear Medicine community's concerns with some of the NRC's medical use regulations contained in 10 CFR Part 35. We deeply appreciate your time and interest in our concerns and proposed solutions.

I wanted to follow up on some details and facts as promised during our visit. As you know, we believe the Nuclear Medicine community has an excellent safety record and that the misadministration rate in our field is exceedingly low when compared to other medical specialties. Our misadministration rate of about 1 in 10,000 is approximately 1,000 times lower than the diagnostic radiology mistake (essentially a misadministration) rate and about 2,000 times lower than the non-radioactive drug misadministration rate. More importantly, in terms of radiation absorbed dose, Nuclear Medicine procedures generally result in 5 to 10 or more times less absorbed dose than many comparable radiology procedures; in terms of safety of drugs, our radioactive drugs are the safest drugs used in the United States today. (see accompanying table).

The NRC uses the figure of about 100 mrem whole body radiation dose on average per nuclear medicine misadministration. If this is judged to be a significant risk to the public health and safety, then perhaps we should encourage the evacuation of a large part of Colorado, including Denver, where each member of the population receives the equivalent of one Nuclear Medicine misadministration per year just from extra background radiation!

I would like to emphasize that the vast majority of Nuclear Medicine studies performed are diagnostic, and pose no real or theoretical harm. In fact, the total national radiation absorbed dose from Nuclear Medicine misadministrations per year is 100 rem; even if 100 rem were given to one individual, it would not kill him (it seems that the only individuals who do receive that kind of radiation are radiographers with general licenses, and they are hardly regulated at all).

As we discussed, Nuclear Medicine physicians do perform some radiopharmaceutical therapy procedures, where the potential for harm is greater. However, I have been practicing Nuclear Medicine since 1969 and have never encountered a therapy misadministration. We would like to clarify the fact that brachytherapy and teletherapy are performed by radiation therapists, and this is completely separate from Nuclear Medicine. Some of our therapy procedures

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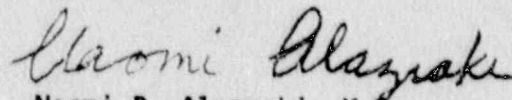
include NaI - 131 (thyroid),  $\text{Na}_3\text{PO}_4\text{-P-32}$  (bone marrow disorders), and chronic phosphate P-32 (intracavitary metastases), but these procedures involve radioactive drugs as opposed to encapsulated radionuclides, radiation from sealed sources, or radiation produced from machines. Nuclear Medicine physicians and our organizations do not impact on the practice of brachytherapy or teletherapy.

The Society of Nuclear Medicine and the American College of Nuclear Physicians share with the NRC the goal of providing the highest quality Nuclear Medicine services to patients. However, we believe that existing programs and mechanisms to assure quality control are already in place and that the NRC should not embark upon new programs and regulations that duplicate those already in place. We are always willing, however, to work with the NRC to modify regulatory initiatives to achieve a mutually acceptable and hopefully workable regulatory framework that protects the public and facilitate for optimal medical care.

We look forward to hearing more about the NRC's Visiting Fellows program, and believe that the NRC would benefit greatly from having direct medical input to staff. The Society and College would be happy to assist the NRC in making this program work.

Once again, I appreciate the opportunity to meet with you to discuss these important issues. I hope you and your staff will feel free to call upon me or other SNM/ACNP members or staff if you ever have any questions about Nuclear Medicine.

Sincerely,



Naomi P. Alazraki, M.D.  
President-Elect, SNM

Enclosure

cc: Richard A. Holmes, M.D., President, SNM  
Capt. William H. Briner (Ret.)  
E. William Allen, M.D., President, ACNP  
Virginia M. Pappas  
Carol A. Lively

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COMPARATIVE DEATH RATES

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NON-RADIOACTIVE DRUGS.....	10-40/10,000
PARENTERAL CONTRAST MEDIA.....	0.25-1/10,000
PULMONARY ANGIOGRAPHY.....	25/10,000
PENICILLIN.....	2/10,000
HEPARIN.....	9.5/10,000
ANTINEOPLASTICS.....	58/10,000
BLOOD TRANSFUSIONS.....	0.03/10,000
RADIOPHARMACEUTICALS.....	<0.002/10,000*

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\*Assumes under 20 deaths in the whole history of nuclear medicine and 100,000,000 total studies.

Sources: Porter, J., Jick, H. "Drug-Related Deaths Among Medical Inpatients." JAMA, Vol. 237, February 28, 1977, pp 879-881.

Shapiro, S., Slone, D., Lewis, G. P., et al. "Fatal Drug Reactions Among Medical Inpatients." JAMA. Vol. 216, 1971, pp467-472.

Armstrong, B., Dinan, B., Jick, H. "Fatal Drug Reactions in Patients Admitted to Surgical Services," American of Surgery, Vol. 132, pp.643-645, 1976.

Adverse reaction data for radiopharmaceuticals compiled by the Society of Nuclear Medicine.