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October 19, 1989

Secretary of the Commission
 U.S. Nuclear Regulatory Commission
 Docketing and Service Branch, Docket #PRM-35-9
 Washington, DC 20555

Dear Mr. Secretary:

I am a practicing Nuclear Medicine physician at St. Vincent Hospital in Worcester, Massachusetts. The revised 10 CFR 35 regulations of April 1987 are deeply disturbing. I strongly support the petition for rule making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The current restrictions prevent me from providing individualized care for my patients.

Several times limitations on the amount of allowable activity has caused us to engage in studies worthless to the patient when they are unable to hold still for a prolonged period of time. When the risk of harm from increased radiation dose is miniscule and the benefits from a good study are great, my judgment should be allowed to override the arbitrary impositions of the NRC.

Furthermore, many radio-pharmaceuticals are useful in studies that have not been specifically approved by the FDA. The high cost of gaining FDA approval for each new indication results in major restrictions of utilization to the patients detriment. Certainly, in every other phase of practice diagnostic agents are administered at the physicians discretion under FDA regulations and State Medicine and Pharmacy Laws. The regulatory provisions in part 35 directly interfere with the practice of medicine which contradicts the NRC's medical policy statement against such interference.

I cannot believe that the NRC consciously promulgated regulations to jeopardize the care of patients. My thirty years experience with the NRC leaves me to conclude that this agency which does an excellent job of protecting the general population and the radiation worker is not very knowledgeable about the practice of medicine and its benefits and limitations. The multitude of better qualified boards regulate medical practice.

I, therefore, repeat that I strongly urge the NRC to adopt the ACNP/SNM petition for rule making as quickly as possible.

Sincerely,

Melvin Farmelant

Melvin Farmelant, M.D.
 Director of Nuclear Medicine

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 A Major Affiliated Teaching Hospital of The University of Massachusetts Medical School