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

Dear Mr. Secretary:

The Petition for Rule Making filed by the American College of Nuclear Physicians and The Society of Nuclear Medicine has my strong support. I am a practicing Nuclear Medicine Physician at the University of Kansas Medical Center in Kansas City, Kansas. The revised 10 CFR 35 Regulations of April 1987 governing the use of byproduct material will significantly interfere with our ability to practice Nuclear Medicine and Nuclear Pharmacy.

The regulatory provisions of Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4) prohibits practices which are legitimate and legal under FDA Regulations, State Pharmacy acts and State Healing Arts Boards. Current NRC regulations have legislated the FDA package insert to be the NRC regulation. The NRC has assumed authority over the practice of medicine and pharmacy, areas which clearly were the regulatory domains of the State.

The package insert describes the status of a product and certain uses which have achieved some level of general approval. The FDA allows and encourages other clinical uses of previously approved drugs. This new use of older agents reflects progress on the part of Nuclear Medicine in finding safe and effective diagnostic uses for these older agents. This is the domain of the practice of medicine and it is regulated by the States and has not been, up until now, under NRC regulations. Determining the patency of Levine shunts, determination of gastric emptying time, the labeling of the patient's white blood cells with technetium-labeled fat soluble radiotracers are but three areas which provide important valid safe diagnostic information, not obtainable by other means, and which require some deviation from the FDA package insert.

The current NRC regulations conflict with the physician's obligation to practice medicine. The regulation is not in the best interest of patient care. The area is already quite regulated through the FDA, State Boards of Pharmacy, Board of Medical Licensure and the Joint Commission on Accreditation as well as institutional and departmental quality assurance requirement. The NRC's concern with "misadministration" in this area of diagnostic radiopharmaceuticals is clearly a regulatory over-kill. It is my understanding that the data which the NRC has used to raised concern over misadministrations clearly shows an amazingly small number of misadministration given the number of doses involved. In addition, "misadministrations", while in error and something to be avoided, can be shown to

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have no demonstrable health effect with the exception of therapeutic uses of radioisotopes. I join the ACNP and the SNM in urging the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences, or the NCRP, to assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I believe that the results of such a study would demonstrate the NRC's efforts are unnecessary, not cost effective in relation to the extremely low health risk of these diagnostic procedures.

I strongly urge the NRC to adopt the ACNP/SNM Petition for Rule Making as soon as possible.

Sincerely yours,

David F. Preston, M.D.
Professor of Diagnostic Radiology
Division of Nuclear Medicine

DFP/p