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November 17, 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 writing in strong support for the Petition for Rule Making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I find the current regulations as dictated by revised 10 CFR 35 to be unduly restrictive to my practice of nuclear medicine and to the development of nuclear medicine in general.

I currently practice nuclear medicine at Kettering Medical Center in Dayton, Ohio and enjoy a strong reputation among my colleagues in the medical staff. A main reason for their respect is my ability to use nuclear medicine procedures to help resolve clinical problems and provide useful information in a safe, timely and cost-effective manner. Although we currently do a good job many gaps remain in our diagnostic and therapeutic armamentarium. Our ability to fill those gaps are in large part hampered by the NRC regulations added on to those that already exist in other regulatory agencies (such as the FDA).

NRC regulations significantly delayed the use of Tc-99m DTPA for aerosol ventilation studies even though the radioisotope had long been approved by the FDA. Currently I am restricted from using that radioisotope for studies of cerebrospinal fluid flow, being forced instead to use a much more expensive and less readily available material (Indium-111 DTPA). This results in delayed diagnosis, higher radiation exposure and increased expense for the patient.

In regards to the aerosol ventilation scan, in many patients the study would best be done using Tc-99m Sulfur Colloid rather than DTPA, however I am restricted from doing so by NRC regulations. The patients thus receive a suboptimal test only because of needless restrictive regulations. This places the patient at risk of receiving an inaccurate diagnosis with resultant increased morbidity.

I could go on with more examples but these few illustrate the actual disservice done to our patients by rules which allegedly were created to protect them. The NRC needs to recognize that FDA regulations, State medicine and pharmacy laws, JCAHO, in-hospital radiation safety committee and institutional QA procedures adequately monitor pharmaceutical availability and usage for patient care and research. I feel that the current NRC practice contradicts its own Medical Policy against medical

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interference and is detrimental to patient care.

It appears that the primary focus of the NRC is to prevent mistaken, needless, excessive, or dangerous radiation exposure to our patients through strict adherence of the rules of the NRC (specifically 10 CFR 35 regulations). I agree with the goal but feel that the above mentioned groups along with the professional judgement of physicians and pharmacists can more than adequately ensure the proper administration of radiopharmaceuticals. With the current limitations of resources available and the Federal government's efforts to reduce medical costs, regulations that are unnecessary and redundant can only divert health care providers from their primary mission of caring for patients and result in lower quality care and increased cost to the medical care system.

In closing, we should eliminate those rules and regulations which are not needed to ensure safe nuclear medicine practice and optimal patient care. I therefore strongly urge the NRC to adopt ACNP/SNM Petition for Rulemaking without further delay.

I thank you in advance for your attention and understanding.

Sincerely,

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