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NUCLEAR MEDICINE

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October 19, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch,
Docket #PRM-35-N
Washington, D.C. 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 am in the full-time practice of nuclear medicine at Roseville Hospital in Roseville, California. I have great concern about the revised 10 CFR-35 regulations (effective April, 1987) governing the medical use of by-product material since they significantly and, at times, negatively impact upon my ability to practice high-quality clinical nuclear medicine.

To limit the use of radiopharmaceuticals to only those uses listed in the manufacturer's package insert infringes upon the clinical practice of medicine and limits my ability to provide the highest quality of patient care individualized to a specific patient need. Additionally, the current regulatory provisions in Part 35 do not allow practices which are legal and allowable under FDA regulations, as well as state medicine and pharmacy laws. These regulations currently impinge upon the practice of medicine and appear to directly contradict the NRC's medical policy statement against such interference. The NRC appears to have purposely avoided soliciting comments and expertise from the Society of Nuclear Medicine, the American College of Nuclear Physicians, the American College of Radiology, the American Medical Association, state medical boards and state pharmacy boards, particularly in the field of quality assurance, training, and experience.

While the NRC's primary regulatory focus appears to be directed toward misadministrations of radiopharmaceuticals, underlying assumptions made by the NRC are unsubstantiated and show no scientific basis for assuming that such misadministrations pose a serious threat to the public health and safety. I would strongly urge the NRC to pursue a comprehensive study under the auspices of the National Academy of Sciences or the NCRP to assess the radio-biological effects of misadministrations from diagnostic and therapeutic nuclear medicine studies. I strongly believe that the results of such a study would demonstrate that the NRC's efforts to impose additional and more stringent regulations are unnecessary and certainly not cost-effective when the extremely low health risks of nuclear medicine diagnostic and therapeutic studies are considered.

I would urge the NRC to adopt the ACNP/SNM petition for rule making as expeditiously as possible.

Sincerely,

Robert F. Carretta

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