PETITION RULE PRM 35-9

(54FR 38239)

10-12-89

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Secretary of the Commission. U.S. Nuclear Regulatory Commission Washington, DC 20555

Attn: Docketing and Service Branch

Reference: Concurrence with petition by American College of

Nuclear Physicians and Society of Nuclear Medicine.

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BUCKETING TOTAL

Nuclear Physicians by virtue of their training, experience and responsibility to deliver quality patient care, should be allowed to determine appropriate diagnostic and therapeutic applications of radiopharmaceuticals. Nuclear Pharmacists by virtue of their training and professional responsibility should be allowed to compound and dispense quality, efficacious radiopharmaceuticals upon legal prescription of the Nuclear Physician.

By congressional mandate, the practices of medicine and pharmacy are exempt from FDA's manufacturing and distribution regulations, but they are not exempt from FDA's regulations forbidding misbranding and adulteration. Since the FDA is the enforcement arm of the drug quality standards published in the United States Pharmacopoeia, the NRC should be relieved of its responsibility for controlling an area of the practice of medicine and pharmacy for which it has minimal expertise.

Current NRC regulations severely restrict the practice of medicine and pharmacy which ultimately compromises optimal delivery of quality nuclear medicine care and the implementation of nuclear medicine research.

Physicians and Pharmacists should be allowed to practice Nuclear Medicine and Nuclear Pharmacy and activities permitted by FDA regulation should be allowed under NRC regulation

I totally concur with the petition submitted by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The NRC should revise its regulations to give cognizance to the appropriate scope of the practice of medicine and pharmacy.

Affred W. Itell

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