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October 18, 1989 (54 FR 38239)

Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing Service Branch

Subject: 10 CFR Parts 30,33, and 35 [Docket No. PRM-35-9]

Mr. Chilk:

I wish to take this opportunity to provide this statement of support for the petition for rule making submitted by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) and dated June 5, 1989.

I am a practicing board certified nuclear pharmacist who is very concerned that current NRC regulations governing the medical use of radiopharmaceuticals are detrimental to the provision of health care services by both physicians and pharmacists. Therefore, I request that the Commission revise its regulations to give cognizance to the appropriate scope of the practices of medicine and pharmacy. The applicable regulations must allow nuclear medicine physicians and nuclear pharmacists to reconstitute non-radioactive kits differently from the method recommended by the manufacturer; allow nuclear medicine physicians and nuclear pharmacists to prepare radiopharmaceuticals whose manufacture and distribution are not regulated by FDA; and permit nuclear medicine physicians to determine appropriate diagnostic and therapeutic applications of radiopharmaceuticals.

I firmly believe that current NRC regulations prevent physicians and pharmacists from appropriately practicing their professions. Physicians must be allowed to practice medicine as currently permitted to by the FDA and by their state boards of medicine. Nuclear pharmacists have been disenfranchised as a professional entity because activities that are permitted by FDA and the state boards of pharmacy are not allowed under current NRC regulations. I strongly believe that the NRC has inappropriately involved themselves in the professional activities of licensed physicians and pharmacists. I also believe that, as professional practitioners, physicians and pharmacists must reserve their right to exercise professional judgement as appropriate to assure optimal patient care services.

In closing, I believe that regulatory incompatibility between the NRC regulations, FDA regulations, and state pharmacy and medicine laws is causing serious problems in the optimal delivery of quality nuclear medicine care and the implementation of nuclear medicine research. Consequently, I fully support the ACNP/SNM petition for rule making and its proposed amendments and request that the NRC take immediate steps to solve this important problem.

Sincerely submitted,

Neil A. Petry, R.Ph., M.S., B.C.N.P.
Director, Nuclear Pharmacy

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