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The University of Kansas Medical Center

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October 18, 1989

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

Dear Mr. Secretary:

This letter is written to express strong support for the Petition for Rule Making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am currently the Technical Director of the Nuclear Medicine Division at the University of Kansas Medical Center in Kansas City, Kansas. It is my very strong feeling that the revision of 10 CFR 35 Regulations put into effect in April 1987 will significantly impair our ability to practice nuclear medicine and nuclear pharmacy.

Of particular concern are the Regulatory provision of Part 35 (35.100, 35.200, 35.300 and 35.17(a)(4) prohibiting the practices which are legitimate and legal under FDA Regulations, State Pharmacy Acts and State Healing Arts Boards. In basic terms the current NRC regulations have given the NRC authority to regulate the use of the medicines according to the FDA package insert, which are substantially more constrictive than those practices and procedures that have in the past been quite legal and proper under laws governing the practice of medicine and pharmacy.

These regulations will have a significantly negative impact on the ability of the Nuclear Medicine profession to provide what has been in the past standard diagnostic and therapeutic procedures to patients. Occasionally our procedures are modified slightly to accommodate a particular patient's needs in a safe and effective way in order to provide specific results from individual patient studies. These procedures are all performed and documented according to both state and national accreditation and review processes. We fall under the State of Kansas Radiation Safety Review as well as the Joint Commission on Accreditation, College of American College of Pathologists' Review, State Boards of Pharmacy, Board of Medical Licensure as well as many other departmental and institutional quality assurance and safety regulations.

I feel these NRC regulations will produce much more restrictive and damaging results hindering physician judgement in rendering patient care decisions, while at the same time failing to address their goal of reducing misadministrations.

I strongly urge that the ACNP/SNM Petition for Rule Making being adopted by the NRC as soon as possible.

Sincerely yours,

Mel Allen, MBA, RNMT
Clinical Supervisor
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