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PETITION RULE PRM 35-9

(54FR 38239)

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

Attention: Docketing and Service Branch, RE: Docket No. PRM-35-9

Ladies and Gentlemen:

This letter is in support of the American College of Nuclear Physicians and the Society of Nuclear Medicine; Petition for Rulemaking. This Petition for Rulemaking is necessary to clarify the ability of pharmacists and physicians to practice pharmacy and medicine.

Nuclear pharmacists compound and dispense radiopharmaceuticals upon the order of a licensed nuclear physician. Both nuclear pharmacists and physicians are trained professionals. The physician has the clinical expertise to decide what study a particular patient needs and what radiopharmaceutical should be used. The nuclear pharmacist has the expertise to compound the radiopharmaceutical the physician orders. The practice of medicine and pharmacy is clearly governed by the States regardless of specialty. NRC regulation of the practice of these professionals must be avoided since it will hamper the physicians and pharmacists ability to deliver quality patient care.

Of particular interest is the NRC's recent reinterpretation of license conditions for nuclear pharmacies and regulations for nuclear medicine licensees. At issue is a requirement to strictly follow the manufacturer's instructions for preparation of radiopharmaceuticals as printed in the manufacturer's package insert. The package insert information should be considered as a guideline in the preparation and use of any product, but pharmacists must have the ability to use professional judgement in compounding to assure the prescribing physician receives the most efficacious product for his/her patient.

Physicians must also prescribe products which are most appropriate for their individual patients. A strict following of the package insert would delay or prevent diagnosis of disease in some patients. The quality of medical care for these patients could be greatly increased if their diagnoses were supplemented with nuclear medicine studies.

This Petition for Rulemaking is necessary to clarify that physicians and pharmacists have the flexibility to use radiopharmaceutical products as necessary and appropriate in the diagnosis and treatment of patients. Death, injury, or inappropriate treatment of patients may result from any mandated, verbatim following of the package insert instructions.

I urge you to strongly consider the ACNP/SNM's Petition for Rulemaking. Its adoption would clarify the ability of Nuclear Medicine Physicians and Nuclear Pharmacists to give the best patient care.

Sincerely, *Paul D. Sale*

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