

DOCKET NUMBER PETITION RULE PRM 35-9

(54 FR 38239)

November 13, 1989

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

Attention: Docketing and Service Branch

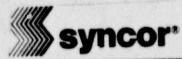
RE: Docket No. PRM-35-9

Ladies and Gentlamen:

This letter is in support of the American College of Nuclear Physicians and the Society of Nuclear Medicine; Petition for 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. what study a the clinical expertise to decide has needs and what radicpharmaceutical should be patient The nuclear pharmacist has the expertise to compound the radiopharmaceutical the physician orders. The practice medicine and pharmacy is clearly governed by the States regardless NRC regulation practice of these of the of specialty. professionals must be avoided since it will hamper the physicians and pharmicists ability to deliver quality patient care.

the NRC's recent reinterpretation of Of particular interest is pharmacies and regulations for license conditions for nuclear nuclear medicine licensees. At issue is a requirement to strictly instructions follow the manufacturer's radiopharmaceuticals as printed in the manufacturer's package The package insert information should be considered as a quideline in the preparation and use of any product,



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but pharmicists 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.