



INDIANA UNIVERSITY

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SCHOOL OF MEDICINE

DEPARTMENT OF RADIOLOGY  
University Hospital X98  
926 West Michigan Street  
Indiana University Medical Center  
Indianapolis, Indiana 46223  
(317) 274-1866

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October 20, 1989

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

Dear Mr. Secretary:

I wish to give my very strong support to the petition filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine regarding proposed amendments to NRC Regulations 10 CFR Parts 30, 33 and 35. I am a practicing Nuclear Medicine physician at the Indiana University Medical Center in Indianapolis, Indiana. The regulations restrict my practice of nuclear medicine in that they keep me from performing valuable studies which are permitted under FDA regulations but which are not specifically described in the manufacturers' package inserts.

I feel that I am qualified as a board-certified nuclear physician to deviate from the package insert instructions when I feel it is in the best interests of my patient. The FDA supports such actions. The manufacturers have not, nor are they expected, to anticipate and apply for approval for every possible use or means of administration of their products. In the past, deviations from the package insert instructions have led to numerous valuable procedures which are currently in wide use.

It must be noted that the radiation risk from diagnostic nuclear medicine studies is very small, and the benefits of such studies greatly outweighs the risks.

I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking.

Sincerely,

*Bernard E. Oppenheim, M.D.*  
Bernard E. Oppenheim, M.D.  
Professor of Radiology

BEO/jd