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University of Cincinnati
Medical Center

University of Cincinnati Hospital
231 Goodman Street
Cincinnati, Ohio 45267-0577

Eugene L. Saenger Radioisotope Laboratory
Mail Location #577
TELEPHONE (513) 558-4282

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October 18, 1989

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

Dear Mr. Secretary:

I am writing to express our support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am the Director of the Eugene L. Saenger Radioisotope Laboratory at the University of Cincinnati Hospital in Cincinnati, Ohio. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they impair our ability to practice nuclear medicine.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. The package insert was never intended to prohibit physicians from deviating from it for other indications; on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA and there is simply no economic incentive to do so.

Currently, the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4)) do not allow practices which are legitimate and legal under FDA regulations and State medicine and pharmacy laws. These regulations therefore inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

Very sincerely yours,

Harry R. Maxon III, M.D.
Professor and Director

HRM/jc:

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