THE WASHINGTON HOSPITAL CENTER

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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 my support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I practice Nuclear Medicine at Washington Hospital Center in Washington, D.C. I am concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they impair my ability to practice high-quality Nuclear Medicine.

The NRC should recognize that the FDA does allow, and 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, manufactures 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 32,300 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.

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110 IRVING ST., N.W., WASHINGTON, D.C. 20010

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations, particularly those involving diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety, I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences or the NCRP, to assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRC'S efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risks of these studies.

Sincerely,

Dean Rodman, M.D.
Associate Chairman
Department of Nuclear Medicine
Washington Hospital Center