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October 17, 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 write to express my strong support for the Petition for Rule Making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing Nuclear Medicine Physician at the University of Kansas Medical Center in Kansas City, Kansas. I am concerned that the revised 10 C.F.R 35 Regulations put in effect in April of 1987 governing the medical use of byproduct material will significantly impact our ability to practice nuclear medicine and nuclear pharmacy.

Specifically, the Regulatory provisions of Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4) prohibit practices which are legitimate and legal under FDA Regulations, State Pharmacy Acts and State Healing Arts Boards. In effect, the current NRC regulations have legislated the FDA package insert into the NRC regulations. Thus, the NRC has assumed authority over the practice of medicine substantially beyond those practices and procedures that are and have been quite legal and proper under laws governing the practice of medicine and pharmacy.

I am a former member and Chairman of the Food and Drug Administration's Radioactive Drug Advisory Committee, and served an additional 9-years as Consultant to the Committee for the FDA. I have filed over a dozen IND (Investigational New Drug) applications and am quite familiar with the provisions of the Food, Drug and Cosmetic Act and drug labeling as they pertain to the practice of medicine. The FDA allows and encourages other clinical uses of approved drugs and discourages the submission of physician-sponsored INDs that describe new indications for approved drugs. Deviation from the package insert is necessary for the growth and development of new diagnostic and therapeutic procedures. In our own practice at the University of Kansas Medical Center, it is often in the patient's best interest that a radiopharmaceutical be given to a patient by a route of administration different from that described in the original FDA package insert, and on occasion in levels of radioactivity greater than those suggested in the package insert. Studies of Levine shunt patency and passage of radiolabeled food through the stomach and GI tract are examples of studies which provide important diagnostic information not obtainable by other means, but which require some deviation from the FDA package insert.

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The current NRC regulations conflict substantially with the physician's traditional right and obligation to practice medicine, in this case Nuclear Medicine, in the best interests of each and every patient we see. The FDA, State Boards of Pharmacy, Boards of Medical Licensure and the Joint Commission on Accreditation as well as institutional and department quality assurance provide constant and professional overview of our practices. The NRC's concern with "misadministrations", particularly in the area of diagnostic radiopharmaceuticals, actually poses a more serious threat to public health and safety because NRC regulations interfere with the highest level and quality of patient care. I join the ACNP and SNM in urging 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 stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risk of these diagnostic procedures.

I strongly urge the NRC to adopt the ACNP/SNM petition for rule making as soon as possible.

Sincerely yours,

Ralph G. Robinson, M.D.
Professor of Diagnostic Radiology
Head, Division of Nuclear Medicine

RGR/p