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October 19, 1989

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

Dear Mr. Secretary:

I am very concerned over the revised 10 CFR 35 regulations (effective April, 1987) regulating the medical use of byproduct material in that I am afraid that they will adversely impact on my ability to practive high quality nuclear medicine and provide optimal patient care. Therefore, I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and Society of Nuclear Medicine.

Each patient presents unique problems and questions of diagnostic concern. It is not uncommon to deviate from the stated FDA-approved indications when performing a study. For example, at times agents that are approved for renal evaluation may actually be injected intravenously for the evaluation of a large vessel, such as the aorta or iliac vessels. This additional information obtained is often critical when compared with correlative nuclear medicine and/or other radiographic studies.

Fortunately, the FDA does allow and often encourages other clinical uses for approved drugs and actually discourages submission of physician-sponsored INDs that solely describe new indications for approved drugs. The NRC should recognize this fact. The package insert alone was not intended to prohibit physicians from deviating from the rather small number of indications included in it. On the contrary, deviation is necessary for growth and development of new and important diagnostic and therapeutic procedures. Clinical research based upon such deviation often makes up a large portion of the articles in the most prestigious, peer reviewed journals. The FDA rarely revises package inserts when new indications are discovered, as manufacturers do not go back to the FDA for such revision as there is no economic incentive to do so.

Currently, portions of part 35 [35.100, 35.200, 35.300 and 33.17(A)(4)] preclude practices considered legal and legitimate under the FDA and state medicine and pharmacy laws. Therefore, these regulations interfere with my ability to practice medicine and incidentally contradicts NRCs own medical policy statements against such interference. I would hope the NRC would rely on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, radiation safety committees, institutional Q/A review procedures, and most importantly, on the professional judgement of physicians and pharmacists who are well-trained to administer and prepare these materials.

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The NRC appears to base its regulatory focus on unsubstantiated assumptions regarding misadministrations, specifically that misadministrations involving

diagnostic radiopharmaceuticals poses a serious threat to public health and safety. I would think the NRC should pursue a comprehensive study following reputable scientific guidelines and under the auspices of a reputable scientific panel, such as the National Academy of Sciences or the NCRP, to assess the adverse impact of misadministrations of nuclear medicine diagnostic and therapeutic studies. I, as well as many of my collegues, firmly believe that such a well planned and executed studies will demonstrate that the NRCs efforts to impose more and more regulations are unnecessary, are not cost effective, and will inhibit my ability to practice effective nuclear medicine.

I urge the NRC to adopt the ACNP/SNM petition for rulemaking as quickly as possible.

Sincerely,

D. Kahn, M.D.

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