Richland Memorial Hospital

December 4, 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 am writing to express my strong support for the Petition for Rulemaking filed
by the American College of Nuclear Physicians and the Society of Nuclear
Medicine. I am the Medical Director of the Nuclear Medicine department at
Richland Memorial Hospital in Olney, Illinois. I am deeply concerned over the
revised 10 CFR 35 regulations (effective April, 1987) governing the medical use
of byproduct materials as they significantly impact my ability to practice
high-quality Nuclear Medicine and Nuclear Pharmacy and are preventing me from
providing optimized care to individual patients.

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 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.

Finally, I would like to point out that highly restrictive NRC regulations will
only jeopardize public health and safety by: restricting access to appropriate
Nuclear Medicine procedures; exposing patients to higher radiation absorbed
doses from alternative legal, but non-optimal, studies; and exposing hospital
personnel to higher radiation absorbed doses because of unwarranted, repetitive

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procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. Instead, the NRC should 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, the professional judgement of physicians and pharmacists who have been well-trained to administer and prepare these materials.

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.

In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

Lawrence J. Knox, M.D.
Medical Director - Nuclear Medicine

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Addendum: I have the oldest license in the State of Illinois for the use of radioactive materials and, as such, I would appreciate your consideration in this matter.

LJK