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TEMPLE UNIVERSITY HOSPITAL
DIVISION OF NUCLEAR MEDICINE
DEPARTMENT OF DIAGNOSTIC IMAGING

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

Gentlemen:

I would like to express to you my strong support for the Petition for Rulemaking filed by the the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing physician in the specialty of Nuclear Medicine at Temple University Hospital in Philadelphia, Pennsylvania. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of by-product material as these regulations significantly impact on my ability and other physicians practicing Nuclear Medicine to continue to provide high-quality Nuclear Medicine services.The proposed changes will prevent me from providing appropriate and optimal care to a wide range of patients.

Currently I use a number of radiopharmaceuticals for diagnostic purposes in clinical practice under a broad license agreement and approved investigational protocols. These radiopharmaceuticals have been in use for many years for providing diagnoses that are not approved uses named in the manufacturers' inserts.It would be a tragic error to limit the services that we currently are providing.

The proposed changes have major implications for pediatric medicine.Most manufacturers do not list pediatric uses for their agents, yet these agents are used in children's hospitals throughout the United States! Strict adherence to the manufacturers' recommendations would virtually stop all pediatric 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. For example, a number of radiopharmaceuticals for intravenous use are used orally for studies of gastrointestinal motility throughout the country. 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 and 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. There is no economic incentive to do so because of the extremely high costs associated with the application for additional approvals.

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Currently, the regulatory provisions in Part 35 [35.100, 35.200. 35.300, and 33.71(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.

Such highly restrictive NRC regulations will only jeopardize public health and safety since access to appropriate Nuclear Medicine procedures will be restricted; patients will be exposed to higher radiation absorbed doses from alternative legal, but non-optimal studies; and, hospital personnel will be exposed to higher radiation absorbed doses because of unwarranted, repetitive 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 quality assurance review procedures, and most importantly, the professional judgment of the physicians and pharmacists who have been well-trained in the administration and preparation of these materials.

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 welfare 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 radiobiologic effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies.The results of such a study can only 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.

It is essential for the continuation of optimal patient care that the NRC adopt the the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

Alan H. Maurer, M.D.