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Secretary of the Commission
US 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 Soicety of Nuclear Medicine. I am a practicing physician in Atlanta. I am deeply concerned over the revised 10 CFR 35 regulations (effective April 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine and are preventing me from providing optimized care to individual patients.

For example, I am exploring the use of human-human monoclonal antibody in the diagnosis and treatment of human maligancny with permission for pilot study granted by the FDA. Present regulations prohibit using a Technetium kit, for example, to label same to conduct distribution studies. As a consequence patients treated with this material are subjected to multiple biopsies for quantitation of binding and evaluation of distribution. This is an absurdity.

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. I as others note there is no economic incentive to return to the FDA to seek revision of package insert (or IND) to include a new indication.

Currently the regulatory provisions in Part 35 (35.100, 35.200, 35.300, 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 inappropirately interfere with the practice of mdeicine despite the NRC's Medical Policy Statement.

I would like to close by noting 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 procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of

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medicine nor should it attempt to regulate radiopharmaceutical use. Instead the NRC should rely on the expertise of the professional judgement of physicians and pharmacists who have been well trained to administer and prepare these materials.

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

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

Sincerely,

Kenneth Alonso, MD, FACP
Director

/k