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

Dear Mr. Secretary:

This letter provides the reason for my critical support for the petition for rule making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine concerning the need to amend CFR, part 35, "Medical Uses of Byproduct Material", (effective April, 1987). I have practiced, and continue to practice, full time Nuclear Medicine for the past 30 years at Research Medical Center, Kansas City, Missouri. I also provide Nuclear Medicine Services for several outreach rural hospitals within the regional area. The present revised 10 CFR regulations governing the clinical use of byproduct material has a critical impact on my ability to provide high quality Nuclear Medicine at the diagnostic, as well as the therapeutic level.

The FDA continues to allow significant other clinical uses of approved drugs and discourages physician sponsored INDs that support new clinical indications for approved pharmaceuticals. The package insert provided by the FDA is not intended to prevent physicians from deviating from it for other conditions, as deviations provide the most essential continued growth in development of new diagnostic and therapeutic procedures in medicine

At this time the regulatory NRC regulations in part 35 (35.100, 35.200, 35.300 and 33.17 (a)(4) do not permit clinical practices which are legitimate and legal under FDA regulations, State regulations and pharmaceutical laws resulting in interference with the practice of medicine. This directly contradicts the NRC medical policy statement against creating such interferences. Overkill by highly restrictive NRC regulations will reduce the quality, health and safety by restricting access to highly effective and proven Nuclear Medicine procedures; thereby, exposing patients to unnecessary repetitive procedures. This also exposes numerous hospital personnel to unnecessary high radiation doses because of the totally unnecessary repetitive procedure. The NRC should not restrict prospective regulations to cover all aspects of medicine, including the regulation of radiopharmaceutical use.

The expertise of the FDA State Boards of Pharmacy, State Boards of Medical Quality Assurance, The Joint Commission on Accreditation of Health Care Organizations, Radiation Safety Committees, institutional QA review procedures, and most importantly, the highly professional judgement of physicians and pharmacists who have been well-trained to

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prepare, evaluate and carefully apply these materials for the most efficient use of diagnostic and therapeutic medicine.

Unfortunately, the NRC's primary concern continues to be based on unsubstantiated assumptions that misadministrations, especially those associated with a diagnostic tracer radiopharmaceuticals, pose a serious challenge to public health and safety.

A comprehensive study by a reputable scientified panel, including the National Academy of Sciences, or the NCRP to document the radiological effects of misadministration in diagnostic and therapeutic Nuclear Medicine should be performed.

I am quite confident of the 30 years of my experience with all forms of radiation that such a study will fully document the NRC's efforts to impose more regulations without documentation are unnecessary and in no way cost-effective in relation to the extremely low level health risks of these procedures.

I, therefore, recommend that the NRC strongly consider the adoption of the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

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