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Mayo Clinic

Rochester, Minnesota 55905 Telephone 507 284-2511

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Lee A. Forstrom, M.D., Ph.D.
Diagnostic Radiology

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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:

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 a practicing Nuclear Medicine physician at the Mayo Clinic, in Rochester, Minnesota. I am very concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material, as they significantly affect my ability to practice high-quality Nuclear Medicine and limit my ability to provide optimized care to individual patients.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and 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 not 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 incentive to do so.

Currently, the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a) (4) do not allow practices which are legitmate and legal under FDA regulations and State medicine and pharmacy laws. These regulations therefore inappropriately interfere with the practice of medicine, which 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 procedures. The NRC should not strive to construct presciptive regulations to cover all aspects of medicine, nor should it attempt to over-regulate radiopharamceutical 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 of Accrediation of Healthcare Organizations, radiation safety committees, radioactive drug research committees, institutional Q/A review procedures, and most importantly, the professional judgement of physicians and pharmacists who have been trained to administer and prepare these materials.

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

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Sincerely,

Lee A. Forstrom, M.D.
Consultant, Nuclear Medicine
Mayo Clinic

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