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

OFFICE OF THE SECRETARY
DOCKETING & SERVICE
BRANCH

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 Pharmacist at Madigan Army Medical Center in Tacoma, Washington. 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 Pharmacy.

For example, I am forced to strictly follow the manufacturers' instructions for kit preparation and expiration times for both diagnostic and therapeutic services, and am forced to follow the instructions for FDA-approved indications, route of administration, and activity levels for therapeutic services. The package insert was never intended to prohibit qualified pharmacists and physicians from deviating from the manufacturers' specific recommendations for using the pharmaceuticals; on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. Manufacturers are not required by the FDA to revise package inserts, and there is simply no economic incentive to do so.

Finally, the NRC should not strive to regulate the use of radiopharmaceuticals. Instead, it should rely on the expertise of established organizations, such as the FDA, State Boards of Pharmacy, and radiation safety committees. Most importantly, the NRC should rely on the professional judgement of qualified pharmacists and physicians who have been well-trained to administer and prepare these pharmaceuticals.

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

Sincerely,

Loren M. Dehnert

Major Loren M. Dehnert
Chief, Nuclear Pharmacy
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