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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 REGULATORY
DOCKETING & SERVICE
BRANCH

Dear Mr. Secretary:

I am a nuclear pharmacist with practice experience in industry, retail (centralized nuclear pharmacy), and hospital nuclear medicine clinical settings. I am currently Vice President of a small radiopharmaceutical manufacturer, and have been active in nuclear pharmacy since 1970. I am also currently Chairman of the Nuclear Pharmacy Group, Section on Specialized Pharmaceutical Services, Academy of Pharmacy Practice & Management of the American Pharmaceutical Association (APhA). APhA represents the third largest health care profession in the United States in which nuclear pharmacists play a very active role.

In response to the September 15, 1989 Federal Register notice of a Petition for Rulemaking change for 10 CFR parts 30, 33, and 35, I STRONGLY SUPPORT THE PETITION filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The revisions will eliminate redundant regulations which unduly transgress the practice of pharmacy and medicine. The acceptance of the petition will allow those individuals so authorized by state and federal licensure to practice their professions, utilize their professional knowledge to ensure the health and wellbeing of the general public and continue to be integrally involved in the research and development of better radiopharmaceuticals and nuclear medical diagnostic and therapeutic procedures.

Pharmacists training encompasses extensive lectures, laboratories and practical experience in the arts of compounding and dispensing; drug formulation, drug synthesis, chemistry and action; and the federal and state laws that govern drug use. Nuclear pharmacists, and in particular, board certified nuclear pharmacists, have further extensive training in the safe and proper use of radiopharmaceuticals. Pharmacists possess the knowledge to safely prepare and modify radiopharmaceutical kits and compound radiopharmaceutical prescriptions as written by physicians, consistent with federal drug and state pharmacy laws.

The practice of pharmacy and medicine is mandated to those individuals who have long been recognized as "experts" in their respective fields, not the NRC! I believe the Commission's interpretation of its congressional mandate is overzealous, not to mention its contradiction to the established Federal Food and Drug Administration's policy concerning the practice of pharmacy

and medicine. In addition, current Commission policy is in direct conflict with state's jurisdictional rights governing professional

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practice. State's rights, is a policy I believe the current and previous Administrations have endorsed as consistent with the philosophical intent of the Constitution. Notwithstanding, the recognition of state's rights by the NRC in the context of Administration policy could have a positive impact on the current national budget

deficit. The Commission's fiduciary obligation to Congress should embrace the state's rights concept as one of it's budget deficit reduction contributions and bring it's basic organizational philosophy more in line with current Administration dogma.

Development of new radiopharmaceutical diagnostic kits and radio pharmaceutical therapeutic agents are impeded by current NRC regulations. Nuclear Pharmacy activities authorized by the FDA and States are preempted by current NRC regulations, and by the Commissions lack of insightful interpretation of the spirit and intent of the law, rather enforcing it to the letter. Although a nuclear pharmacist is authorized by state license to compound and dispense radiopharmaceuticals for patient administration with a prescription, current NRC regulations rigidly restrict such dispensing and compounding to package insert "suggestions", and do not allow for the medical and pharmaceutical professional judgment necessary for the best management of the patient.

I agree with the petitioner's request that the NRC revise it's regulations to allow nuclear pharmacies licensed under 10 CFR 32.72 and 10 CFR 32.73 to compound radiopharmaceuticals. Further more restrictive licenses should be amended by the NRC without charge to the licensee.

Current NRC regulations should be revised to recognize the practice of pharmacy and medicine. Again, I strongly agree with the proposed rulemaking change and urge the Commission to adopt the revisions as petitioned, thereby allowing pharmacist and physicians to practice in accordance with their respective practice standards and professional competence. Adoption of the proposed revisions will also nurture and advance the development of diagnostic and therapeutic radiopharmaceuticals.

Thank you for this opportunity to comment.

Sincerely,

Clyde N. Cole M.S., R.Ph.

CC: Society of Nuclear Medicine
American Pharmaceutical Association
American College of Nuclear Physicians

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