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Diagnostic Radiology

December 1, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket # PRM-35-9
Washington, D.C. 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 nuclear pharmacist at Mayo Clinic in Rochester, Minnesota. 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/Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

For example:

1. The NRC regulations in 10 CFR Parts 35.100, 200, and 300 restrict authorized users to the use of radiopharmaceuticals for which the FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA). Biologicals such as radiolabeled antibodies, like drugs, have approved IND's for investigational use, when biologicals are eventually approved for general use they do not have approved NDA's as do drugs. They have product license application approvals (PLA's). As a result, the use of any PLA's biologicals would be illegal under the NRC regulations.

2. Medical research involving the use of radiolabeled compounds for obtaining basic information regarding metabolism (including kinetics, distribution, and localization), human physiology, pathophysiology, or biochemistry is supervised by the Radioactive Drug Research Committee (RDRC) which is chartered by the FDA. The NRC's existing Part 35 does not permit this category of research to be carried out. However, this is contrary to the fact that all of the RDRC's studies which are currently underway in our institution have been authorized by the NRC.

3. As most package inserts of either IND's or NDA's radiopharmaceuticals state "Safety and effectiveness in children below the age of 18 have not been established.", does this mean that the NRC would not permit the pediatric use of any IND's or NDA's radiopharmaceutical?

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4. The nuclear pharmacist, who is permitted in 10 CFR 35.900(a)(5) to be the radiation safety officer is not entitled to practice his/her primary profession. For diagnostic services, we are forced to strictly follow the manufacturers' instructions for kit preparation. The practice of pharmacy is exempt from the FDA's regulations by Congressional mandate, however this professional practice is not recognized by the NRC.

5. Tc-99m macroaggregated albumin (MAA) is approved by the FDA as a lung imaging agent. The MAA particles are larger than red blood cells and are trapped within the capillary beds of the lung when injected intravenously. If the MAA kit is reconstituted strictly following the manufacturer's instructions, the injection of too many ^{99m}Tc-MAA particles in a standard dose may occur when the kit preparation is close to its expiration time. Since any larger number of ^{99m}Tc-MAA particles would unnecessarily occlude pulmonary capillaries, life-threatening incidents may occur especially in patients with preexisting severe pulmonary diseases.

6. Although P-32 sodium phosphate has been used to treat thrombocythemia since 1937, this particular indication is not listed on the package insert. Therefore, use of P-32 sodium phosphate for treating thrombocythemia is prohibited under 10 CFR Part 35.300.

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. In many cases, manufacturers will never 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 economic 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 legitimate and legal under FDA regulations and State medicine and pharmacy laws. These regulations therefore inappropriately interfere with the practice of medicine/pharmacy, which directly 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, repetitive procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical 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 on Accreditation of Healthcare Organizations, radiation safety committees, institutional Q/A review procedures, and most importantly, the professional judgement of physicians and pharmacists who have been well-trained to administer and prepare these materials.

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

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

Sincerely,

Joseph C. Hung, Ph.D.
Director of Nuclear Pharmacy

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