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Department of Radiology
Section of Nuclear Medicine

December 6, 1989

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 of the Society of Nuclear Medicine. I am a practicing nuclear medicine physician at the Medical College of Wisconsin in Milwaukee, Wisconsin. I am deeply concerned over the revised 10 CFR 35 regulation (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine and are preventing me from providing optimized care to individual patients.

For example, we currently are performing 500 Brain Perfusion studies a year using Technetium 99m HMPAO. If were asked to follow the manufacturers' package insert quality control guidelines, rather then the rapid University of Missouri method, the quality of radiopharmaceuticals would deteriorate significantly. In addition, if we were asked to used the package insert indications for Technetium 99m sulfur colloid, we would no longer be able to performed routine gastric emptying studies.

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 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 legal under FDA regulations and State medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

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Finally, I would like to point out that highly restrictive NCR 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, more should it attempt to of Pharmacy, State Board 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 pharmacist 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 of 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 extremely low health risks of these studies.

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

Sincerely,

B. David Collier, M.D.
Director Nuclear Medicine
Medical College of Wisconsin

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