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November 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 practicing Nuclear Medicine Physician at the West Roxbury VA Medical Center in Boston, MA. I am deeply concerned over the revised 10CFR35 regulations which became effective April, 1987 governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine in a cost effective manner and are preventing me from providing optimized care to individual patients.

For example, gastric emptying study using colloids is usually not included in the technical insert by the manufacturer of such preparation. Patients would be deprived of an important diagnostic test for the lack of stated indication in the technical insert, even though the test is non-invasive, easy to perform and quantitative.

The NRC could recognize and follow the FDA in allowing and encouraging other clinical uses of approved drugs. As I understand, 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. Manufacturers will simply have no economic incentive to go back to the FDA to revise a package insert to include a new indication because it is not required.

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, which directly contradicts the NRC's Medical Policy statement against such interferences.

Finally, I would like to point out that highly restrictive NRC regulations will only jeopardize health care 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

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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 appeared to have been based on the unsubstantiated assumption that misadministrations, in it's rigid definition, 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 re-assess the effects of such "misadministration". 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 counter-productive.

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

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