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

Dear Mr. Secretary:

This letter is in my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I practice Nuclear Medicine as a Nuclear Medicine physician at St. John's Medical Center in Longview, Washington. I am very concerned about the revised 10 CFR 35 regulations (effective April, 1987) which governs the medical use of byproduct material because these regulations significantly impact my ability to practice high-quality Nuclear Medicine and inhibit me from providing optimized care to individual patients.

Over the years, many of the current diagnostic uses of radioactive byproduct materials have been devised and developed in community hospital locations, always under the legal guidelines of FDA regulations and state medicine and pharmacy laws.

The NRC should recognize that the FDA does allow, and often encourages, clinical uses of approved drugs other than those which appear in original package inserts. 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 and development of new diagnostic and therapeutic procedures.

The current 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. I am sure it is not the intent of any regulation to inappropriately interfere with the practice of medicine, but these regulatory provisions do in deed just that, and in doing so directly contradict the NRC's Medical Policy statement against such interference.

There are many consequences of any regulations which restrict and interfere with the practice of medicine. In this instance, the regulations will serve only to jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from alternate legal, but non-optimal, studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted, repetitive procedures.


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Instead of attempting to regulate radiopharmaceutical use, 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, hospital radiation safety committees, institutional quality assurance review procedures, and most importantly, the professional judgement of physicians and pharmacists who have been well-trained to administer and prepare these materials.

Apparently, the NRC's primary regulatory focus with regard to radiopharmaceuticals is based on the unsubstantiated assumption that misadministrations, especially those involving diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety. In this regard, 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 procedures. It is my firm belief that the results of such a study will demonstrate the extremely low health risks of these inadvertent misadministrations, and that efforts to impose more stringent regulations are unnecessary, not cost effective, and may pose a higher health risk than the misadministrations themselves.

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

Sincerely yours,

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