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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 Technologist and have done so for over 20 years. I am the manager and Chief Technologist of the University of KY Medical Center, Nuclear Medicine Division in Lexington, KY. I have been involved in patient care, higher education through our Degree technology students, performed and supervised research in both animals and humans and department and radiopharmacy management.

I am deeply concerned over the revised 10 CFR 35 regulations which govern the medical use of byproduct material as they significantly impact our ability to practice high-quality procedures and prevent both physicians and technologists from providing specific care to specific patients.

For example, for diagnostic services patients who are bleeding internally and specific location of the bleeding site is needed prior to surgical opening of the patient need to have a GI bleed procedure performed with Sulfur Colloid labelled 99m Tc. This is not a clinical indication on the package insert but has been shown to be the best imaging agent on the market for acute GI bleeding localization. Without this test, the surgeon must open the entire abdomen and pelvis to search for a minute site which could be easily missed.

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 physicans from deviating from it for other indications; on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic prodcedures. In many cases, manufactureers will never go back to the FDA to revise package inserts to include new indications since it is not required by the FDA and there is no economic incentive to do so.

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Currently, the regulatory provisions in Part 35 (34.100, 35.200, 35.300 and 33.17(a)(4) do not allow practices which are legitimate and legal under the 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 interference.

Finally, highly restrictive NRC regulations only jeopardize public health and safety by restriciting access to appropriate Nuclear Medicine procedures, exposing patients to higher radiation absorbed doses from alternative but non-optimal studies and exposing technologists and other 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, the State Boards of Pharmacy, State Boards of Medical Quality Assurance, the JCAH, radiation safety committees, institutional Q/A review procedures and the professional judgement of physicians, pharmacists and technologists 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 urge you to pursue a comprehensive study by a reputable scientific panel, 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. An additional study which would be more in public and radiation worker safety would be a study which looked at the incidence of cancers in radiation workers at various levels of exposure.

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

Sincerely,

Judy S. Coon

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Chief Technologist/Manager
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