ALBANY MEDICAL CENTER

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October 18, 1989

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

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 Albany Medical Center in Albany, NY. 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 and are preventing me from providing optimized care to individual patients.

For example, in the package insert for thallium chloride Tl-201 Injection (Mallinckrodt Products Division, Mallinckrodt, Inc., St. Louis, MO 63134) recommends an adult dose of 1-2 mCi for myocardial perfusion imaging. Although this is adequate for planar imaging, tomographic imaging (which was not widely available at the time that thallium was approved or at the time that the package insert was last revised) requires a dose of 3 mCi. If I am forced to strictly follow the package insert, I will not be able to offer the improved sensitivity and resolution of tomographic imaging on thallium scans.

Another example is the use of thallium for evaluating perfusion to brain tumors (astrocytomas) to allow pre-operative staging. This requires the imaging of the brain after an injection of thallium chloride. According to the package insert, thallium is indicated for "myocardial perfusion imaging" and "the diagnosis and localization of myocardial infarction", but is not approved for imaging of brain tumors (Mallinckrodt Products Division, Mallinckrodt, Inc., St. Louis, MO 63134). If I am forced to strictly follow the package insert, I will not be able to offer this important non-invasive diagnostic test, despite the fact that the risk of this test is minimal compared to the risk of dying from an inadequately resected brain tumor.

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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, which directly contradicts with NRC's Medical Policy statement against such interference.

Finally, I would like to point out that highly restrictive NRC procedures will only 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 high 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.

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 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. The NRC should also make this a correspondence item with agreement states.

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 NRCP, 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 the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risk of these studies.

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

Sincerely,

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